SUBCHAPTER 1. GENERAL PROVISIONS1. GENERAL PROVISIONS

7:28-1.1 Purpose and scope

(a) The purpose of this chapter is to prohibit and prevent the use or presence of unnecessary radiation in such manner as to be, or tend to be, injurious or dangerous to the health of the people or the industrial or agriculture potentials of the State, or to the ecology of the State and its wildlife.

(b) Unless otherwise provided by statute or codes, rules or regulations promulgated by the Commission on Radiation Protection, this chapter shall constitute the rules of the Bureau of Radiation Protection, Department of Environmental Protection, and shall govern all persons installing, using, handling, transporting or storing sources of radiation.

7:28-1.2 Construction

These rules shall be liberally construed to permit the Department, the Bureau of Radiation Protection and its various agencies to discharge their statutory functions.

7:28-1.3 Practice where rules do not govern

The Commission may rescind, amend or expand these rules from time to time, in accordance with N.J.S.A. 26:2D-7, Chapter 116, Public Laws of 1958, as amended.

7:28-1.4 Definitions

The following words and terms, when used in this chapter shall have the following meanings unless the context clearly indicates otherwise. Additional words and terms, applicable to a specific subchapter only, will be found in that subchapter.

(a) General Terms:

"Absorbed dose" means the energy imparted to matter by ionizing radiation per unit mass of irradiated material at the place of interest. The special unit for absorbed dose is the rad. (See "Rad" under (b) below.)

"Act" means the New Jersey Radiation Protection Act, Chapter 116, Public Laws of New Jersey 1958, as amended, cited as N.J.S.A. 26:2D-1 et seq.

"Agreement state" means any state with which the United States Nuclear Regulatory Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.

"ALARA" means "as low as is reasonably achievable", taking into account the state of technology and the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to the utilization of radiation in the public interest.

"Area" means a bounded space such as a room, floor, building, plant or any designated geographical entity having physical or imaginary boundaries.

"Average dose rate" means an integrated or accumulated dose of radiation divided by the time over which the integration or accumulation took place or by a specified length of time.

"Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged that no day in any year is omitted from inclusion within a calendar quarter. For purposes of this chapter, no licensee or registrant shall change the method observed by him of determining calendar quarters except at the beginning of a calendar year.

"Commission" means the New Jersey Commission on Radiation Protection.

"Controlled area" means any area to which the access, occupancy and activity of those within are subject to control and supervision for the purpose of radiation protection.

"Dead-man switch" means a switch which can be kept closed only when the operator applies continuous pressure.

"Department" means the New Jersey Department of Environmental Protection.

"Dose equivalent" means a numerical quantity that expresses on a common scale for all ionizing radiation, a measure of the postulated effect on a given organ. It is defined as the absorbed dose in rads times certain modifying factors. The unit of dose is the Rem. (See "Rem" under (b) below).

"Dose rate" means dose per unit time.

"Emergency exposure" means an exposure to radiation of an emergency worker during rescue or other emergency operations.

"Emergency worker" means a member of the owner's staff or of a public voluntary or governmental agency engaged in safety or other emergency operations.

"Exemption" means the administrative relief from the requirements of a substantive rule.

"Healing art" means the practice of any branch of medicine or surgery, any method of diagnosis of human ailment, disease, pain, injury, deformity, mental or physical condition.

"Inspection" means an official examination or observation including but not limited to tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements and conditions of the Department.

"Installation" means a radiation source, with its associated equipment, and the area in which it is housed.

"Instructed individual" means an individual who has received appropriate instructions as to the safe means and methods of performing work with or near radiation sources.

"Ionizing radiation" means any form of radiation which has the capability of ionizing the medium through which it is passing.

"Maximum permissible dose" means the maximum dose to which the body or a particular part of the body of a person shall be permitted to be exposed continuously or intermittently in a stated period of time.

"Nonionizing radiation" means any form of radiation which does not have the capability of ionizing the medium through which it is passing.

"Occupational dose" means exposure of an individual to radiation in a controlled area or in the course of employment in which the individual's duties involve exposure to radiation, provided that "occupational dose" shall not be deemed to include any exposure of an individual to radiation for the purpose of medical diagnosis or medical therapy of such individual.

"Owner" means a person who has title to a radiation source or who possesses a radiation source as a lessee, bailee or pursuant to the terms of a license issued by the Department, by a Federal agency, or by any other state.

"Person" includes an individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, municipality, any state, or other legal entity; and any legal successor, representative agent, or agency of the foregoing.

"Personnel-monitoring equipment" means devices designed to be worn or carried by an individual for the purpose of measuring the dose received; for example, film badges, pocket chambers, pocket dosimeters, and thermoluminescent dosimeters.

"Qualified individual" means an individual suited by training and experience to perform dependable radiation surveys and to determine the degree of radiation hazard.

"Radiation" includes any or all of the following: electromagnetic radiation including radiofrequency, microwave, infrared, visible, ultraviolet, x-ray, or gamma ray; sonic, infrasonic, or ultrasonic waves; and particle radiation including alphas, betas, high energy electrons, neutrons, protons, and other atomic or nuclear particles.

"Radiation area" means an area which is accessible to a worker and in which there exists ionizing radiation at such levels that a major portion of the body would receive in any one hour a dose equivalent in excess of five millirems or in any workweek a dose equivalent in excess of 100 millirems; or levels of nonionizing radiation which exceed the maximum permissible levels of such radiation as specified in the rules and standards established by the Commission.

"Registrant" means a person who is required to register a source of radiation with the Department pursuant to this chapter.

"Research and development" means theoretical analysis, exploration, or experimentation; or the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental production and testing of models, devices, equipment, materials and processes. "Research and development" does not include the internal or external administration of radioactive material, or of radiation, to human beings.

"Shielding" means any material introduced into the path of radiation to reduce the radiation level.

"Source of radiation" means a material, equipment or machine emitting or capable of emitting radiation.

"State" means the State of New Jersey.

"State license" means a license issued by the Department. See also "License" under (b) below.

"Survey" means evaluation for a specific set of conditions or actual or potential radiation or contamination levels by or under the supervision of a qualified individual.

"Unnecessary radiation" means the use of nonionizing or ionizing radiation in such a manner as to be, or tend to be, injurious or dangerous to the health of the people or the industrial or agricultural potentials of the State, as defined in the Radiation Protection Act.

"User" means any individual who personally utilizes or manipulates a source of radiation.

(b) Ionizing radiation terms:

"Airborne-radioactivity area" means an area accessible to workers, in which airborne radioactive materials are present in concentrations such that the values at any time are in excess of the respective values stated in N.J.A.C. 7:28-6.5(a) (Average concentrations) Column B, or prorated values if more than one isotope is present; or values if averaged over the hours of occupancy in any week are in excess of 25 percent of the respective foregoing values.

"Beam-monitoring device" means a device in the useful beam to indicate the relative output of a radiation-producing machine.

"Byproduct material" means any radioactive material except special nuclear material yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or utilizing special nuclear material.

"Contamination" means radioactive contamination.

"Curie" means that amount of a specific radionuclide which disintegrates at the rate of 37 billion atoms per second.

The new International System of Units replaces "curie" with the "becquerel", which means that

amount of a specific radionuclide which disintegrates at the rate of one atom per second. One curie equals 3.7 x 10 E+10 becquerel.

"Diagnostic-type protective tube housing" means x-ray tube housing so constructed that the leakage radiation at a distance of one meter from the target cannot exceed 100 milliroentgen in one hour when the tube is operated at any of its specified ratings.

"High radiation area" means an area which is accessible to workers and in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose in excess of 100 millirem.

"Human use" means the deliberate internal and external administration of radiation or radioactive material to human beings.

"Ionizing radiation-producing machine" means a machine or device capable of generating radiation, such as x-ray producing machines, particle accelerators, high-voltage rectifiers, high-voltage projection equipment, electron microscopes and other types of high-voltage machines.

"Leakage radiation" means all radiation coming from within an ionizing radiation-producing machine except the useful beam.

"License", except where otherwise specified, means a license issued by the United States Nuclear Regulatory Commission or any state for possession and use of radioactive material. See also "State license" under (a) above.

"Medical radiographer" means any individual who, under the supervision of a licensed practitioner, uses medical radiographic equipment on human beings for diagnostic or therapetic purposes.

"Monitoring" means a periodic or continuous determination of ionizing radiation levels or of radioactive contamination.

"Protective barrier" means a barrier of radiation-absorbing material used to reduce radiation exposure. The types of protective barriers are as follows:

"Primary protective barrier" means the material, excluding filters, intercepting the useful beam for protection purposes to reduce the radiation exposure so that it does not exceed two (2) millirems per hour;

2. "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to reduce radiation exposure so that it does not exceed two (2) millirems per hour.

"Rad" means the dose corresponding to the absorption of 100 ergs per gram: a measure of the dose of any radiation to body tissues in terms of the energy absorbed per unit mass of the tissue.

i. The new International System of Units replaces the "rad" with the "gray", which menas the dose corresponding to the absorption of one joule per kiogram. One rad equals 10/2 grays.

"Radioactive material" means a natural or artificially produced substance, solid, liquid or gas which emits ionizing radiation spontaneously.

"Radiographer" means any individual who is in attendance at a site where ionizing radiation sources are being used and who uses or supervises their use in industrial radiographic operations and who is responsible to the owner for assuring compliance with the requirements of this chapter.

"Radiographer's assistant" means any individual who, under the personal supervision of a radiographer, uses sources of ionizing radiation including ionizing radiation-producing machines, radiographic-exposure devices, sealed sources or related handling tools, or survey instruments in industrial radiography.

"Radiographic-exposure device" means any instrument containing a sealed source fastened or

contained therein which the sealed source or shielding thereof may be moved or otherwise changed from a shielded to unshielded position for purposes of making a radiographic exposure.

"Radiography" means the examination of humans or animals, or of the structure of materials by non-destructive methods, utilizing sealed sources or ionizing radiation-producing machines. This term is not intended to apply to techniques such as electron microscopy or x-ray diffraction.

"Rem" means a measure of the dose of any ionizing radiation to body tissue in terms of its estimated biological effect relative to a dose of one rad of x-rays. For the purpose of this chapter, any of the following are considered to be equivalent to a dose of one rem:

i. A dose of one rad due to x, gamma, or beta radiation;
ii. A dose of 0.1 rad due to neutrons or high-energy protons;
iii. A dose of 0.05 rad due to particles heavier than protons and with sufficient energy to reach the lens of the eye.

(1) The new International System of Units replaces the "rem" with the "sievert", which means a measure of the dose of any ionizing radiation to body tissue in terms of its estimated biological effect relative to a dose of one gray of x-rays. One rem equals 10/2 sieverts.

(2) If it is more convenient to measure the neutron flux, or equivalent, than to determine the neutron dose in rads, as provided in ii above, one rem of neutron radiation may, for purposes of this chapter, be assumed to be equivalent to 14 million neutrons per square centimeter incident upon the body; or, if there exists sufficient information to estimate with reasonable accuracy the approximate distribution in energy of the neutrons, the incident number of neutrons per square centimeter equivalent to one rem may be estimated from the following table:

#

Neutron energy (Mev)	Number of neutrons per square centi-meter equivalent to a dose of 1 rem (neutron/cm/2)	Average flux to deliver 100 milli-rem in 40 hours (neutrons/cm/2 per sec.)
Thermal	970 x 10/6	670
0.001	720 x 10/6	500
0.005	820 x 10/6	570
0.02	400 x 10/6	280
0.1	120 x 10/6	80
0.5	43 x 10/6	30
1.0	26 x 10/6	18
2.5	29 x 10/6	20
5.0	26 x 10/6	18
7.5	24 x 10/6	17
10	24 x 10/6	17
10 to 30	14 x 10/6	10

"Roentgen" means the quantity of x or gamma radiation such that the associated corpuscular emission per .001293 grams of air produces, in air, ions carrying one electrostatic unit of quantity of electricity of either sign.

"Sealed source" means a radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

"Shielded position" means the location within the radiographic-exposure device or storage container which by manufacturer's design, is the proper location for storage of the sealed source.

"Source material" means uranium or thorium, or any combination thereof, in any physical or chemical form, or ores which contain by weight 1/20 of one percent (0.05 percent) or more of uranium, thorium

or any combination thereof. Source material does not include special nuclear material.

"Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; U-233 in quantities not exceeding 200 grams; plutonium (Pu) in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: for each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all the kinds of special nuclear material in combination shall not exceed "1", that is, unity as illustrated in the following example:

175 grams Contained		50 grams		50 grams		
U-235	+	U-233	+	Pu	=	1
350		200		200		

"Storage container" means a device in which radioactive materials or sources are transported or stored.

"Total filtration" means the filtration produced by all materials inserted in the useful beam including the materials comprising the tube and its housing, any measured devices in the beam which act as a filter, and any material purposely placed in the beam as filters.

"Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

"Useful beam" means that part of the radiation beam which passes through the window, aperture cone or other collimating device of the tube housing.

"X-ray tube" means an electron tube which is designed for the conversion of electrical energy into x-ray energy.

(c) Non-Ionizing radiation terms:

"Electric field strength" means a field vector quantity that represents the force on an infinitesimal unit positive test charge at a point divided by that charge. The electric field strength is expressed in units of volts per meter (V/m).

"Far field" means a region associated with a radiating source or structure in which the field per unit solid angle is constant. In this region, the field has a predominantly plane wave character, that is, locally very uniform distributions of electric field strength and magnetic field strength in planes perpendicular to the direction of propagation. Generally, the far field region begins several wavelengths distant from the source.

"Fixed radio frequency device" means a device operating at a specific location for a period of 30 days or more.

"Magnetic field strength" means a field vector that is equal to the product of the magnetic flux density and the reciprocal of the permeability. Magnetic field strength is expressed in units of amperes per meter (A/m).

"Microwave oven" means an oven which is designed to heat, cook or dry food through the applications of radio frequency electromagnetic energy, and which is designed to operate at a frequency of 916 MHz or 2.45 GHz.

"Near field" means a region near a radiating source or structure in which the electric and magnetic fields do not have a substantially plane wave character, but vary considerably from point to point. The extent of the near field is only vaguely defined and depends on several factors the most important of

which is the size of the radiating structure with respect to the wavelength of the emitted electromagnetic energy. In general, this distance extends to at least five wavelengths from the radiating device.

"Power density" means the rate of energy transported into a small sphere divided by the cross-sectional area of that sphere. Power density is expressed in units of watts per meter squared (W/m/2), or for convenience milliwatts per centimeter squared (mW/cm/2).

"Power density, plane wave equivalent" means a quantity that is associated with any electromagnetic wave that is equal in magnitude to the power density of a plane wave that has the same electric or magnetic field strength.

"Radiating device" means the antenna, leakage port, or any other part of a device that emits radio frequency electromagnetic energy.

"Radio frequency" means the frequency range of 300 kilohertz (kHz) to 100 gigahertz (GHz).

"Radio frequency device" means any stationary device, machine, equipment or installation which is capable of generating a radio frequency electromagnetic field. This does not include devices which are marketed as consumer products, including, but not limited to citizens band radios, remote controlled toys, remote controlled garage door openers, mobile radio transmitter under authorization of the Federal Communications Commission or any other device specifically exempted by the Commission on Radiation Protection as not presenting a potential hazard or harm to a worker or the public.

"Radio frequency protection guide (RFPG)" means the mean squared electric field strength, the mean squared magnetic field strength, and the equivalent plane wave power density which shall not be exceeded. The RFPG is an upper limit of exposure. Exposure to levels slightly in excess of the RFPG is not harmful, however, such exposure is not desirable. In all cases the exposure shall be reduced to values that are as low as reasonably achievable.

"Specific absorption rate (SAR)" means the time derivative of the incremental energy (dW) absorbed by (dissipated in) an incremental mass (dm) contained in a volume element (dV) of a given density (+63).

$$SAR = \frac{ddW}{dt\ dm} \qquad \frac{ddW}{dt \rho dV}$$

The specific absorption rate is expressed in units of watts per kilogram (W/kg). In view of the proliferation of terms for describing the electromagnetic radiation conditions in biological materials and the discipline oriented interpretation of these terms, it is recommended that the name "specific absorption rate" be used for the quantity defined here, rather than such a name as "absorbed power density per unit mass".

As amended, R.1984 d.337, eff. August 6, 1984.
See: 16 N.J.R. 7(a), 16 N.J.R. 2120(a).
"Fixed radio frequency device" added.
Amended by R.1985 d.502, effective October 7, 1985.
See: 17 N.J.R. 1626(a), 17 N.J.R. 2389(a).
Added definitions "shielded position" and "x-ray tube" in (b).

7:28-1.5 Communications

(a) Communications concerning this chapter, or matters relating to radiation protection, may be addressed to the New Jersey Department of Environmental Protection, Bureau of Radiation Protection, 380 Scotch Road, Trenton, New Jersey 08628.

All emergency notification of incidents involving sources of radiation in this State shall be

immediately reported to either one of the following agencies:

1. Bureau of Radiation Protection

   New Jersey State Department of
   Environmental Protection
   380 Scotch Road
   Trenton, NJ 08628
   Telephone: (609) 292-5586
   Hours: 8:00 A.M. to 4:30 P.M. daily,
   except Saturday, Sunday and Holidays.

2. Communications Officer

   Civil Defense/Civil Defense Bureau
   New Jersey State Police
   W. Trenton, New Jersey 08628
   Telephone: (609) 882-2000
   Hours: 24 hours, seven days.

SUBCHAPTER 2. USE OF SOURCES OF IONIZING RADIATION AND SPECIAL EXEMPTIONS2. USE OF SOURCES OF IONIZING RADIATION AND SPECIAL EXEMPTIONS

7:28-2.1 Authorized use of sources of ionizing radiation

No person shall use, operate, receive, possess, dispose, transfer, install, transport or store sources of ionizing radiation in a manner other than prescribed in this chapter.

No person shall cause, suffer, allow or permit any person to use, operate, receive, posses, dispose, transfer, install, transport or store sources of ionizing radiation in a manner other than prescribed in this chapter.

7:28-2.2 Supervision

(a) All sources of radiation, except those specifically exempted by other sections of this chapter, shall be under the supervision of at least one person who has demonstrated to the Department, or to any agency recognized by the Department, that the person's training and experience satisfies the Department requirements in the following areas of radiation protection:

1. Principles and practices of radiation protection;
2. X-ray and/or radioactivity measurements and monitoring techniques and instruments;
3. Mathematics and calculations basic to the use of radiation;
4. Biological effects of radiation; and
5. Any additional information, qualifications or experience as may be required by the Department.

(b) Any person applying to the Department for a license, registration or certificate pursuant to this chapter, shall include in his application the name of at least one person who has satisfied the requirements of (a) above.

7:28-2.3 Instruction

(a) All persons working in or frequenting the vicinity of radiation-producing machines or radioactive material shall be instructed in the operation and/or use of the sources of radiation and the function and need of any applicable safeguards for the sources of radiation, in accordance with preestablished procedures that have been documented and are on file for review and inspection.

(b) All visitors to controlled areas shall be instructed or escorted to prevent unnecessary exposure to radiation. See N.J.A.C. 7:28-7.4(a)4 (Use of personnel monitoring equipment for visitors).

7:28-2.4 Unattended radiation sources

No person shall cause, suffer, allow or permit any source of radiation to remain unattended and accessible to unauthorized use.

7:28-2.5 Protective devices, systems or mechanisms

(a) No person shall operate a radiation-producing machine or utilize radioactive material whenever shielding for the source of radiation, permits levels of radiation that exceed or have the potential to exceed the radiation limits specified in N.J.A.C. 7:28-6.2 (Radiation levels outside controlled areas).

(b) No person shall operate a radiation-producing machine or utilize radioactive material whenever any device, system or mechanism designed for the protection against radiation required by this chapter has not been installed or is operating improperly.

7:28-2.6 Intentional human irradiation

(a) Only persons licensed or otherwise permitted by law shall arrange for irradiation, application or administration of radiation to a human being or any part thereof, for the purpose of medical diagnosis or treatment.

(b) No provision in N.J.A.C. 7:28 regarding the treatment of human beings in the healing arts is intended to conflict with, supplant or supersede any requirement of the Medical Practices Act of New Jersey.

7:28-2.7 Exemptions for prevention or control of diseases

Rules contained in N.J.A.C. 7:28-6 or 7 and 7:28-13.2 (Reportable radiation incidents) shall not apply insofar as they relate to the intentional exposure of human beings to radiation for the purpose of diagnosis, treatment or investigation for the prevention or control of disease.

7:28-2.8 Special exemptions

The Department, upon application and a showing of hardship or compelling need, with the approval of the Commission, may grant an exemption from any requirement of these rules should it determine that such exemption will not result in any exposure to radiation in excess of the limits permitted by N.J.A.C. 7:28-6 (Permissible Dose Rates, Radiation Levels and Concentrations).

7:28-2.9 Prohibited use

(a) Hand-held fluoroscopic screens shall not be used.

(b) Shoe-fitting fluoroscopic devices shall not be used.

7:28-2.10 Emergency precautions

(a) All owners of radioactive materials shall make a study of potential radiation hazards which may arise from radiation incidents, theft of radio-active materials, fires, floods, windstorms and other disasters within and near the installation with regard to the protection of the following:

1. Tenants and employees;
2. Emergency workers;
3. General public; and
4. Fire fighters and police.

(b) Such studies shall be made for radioactive materials on hand and shall be made in advance of the receipt of additional radioactive materials.

(c) An emergency operational plan, prepared from these studies, shall inform all persons concerned of their duties and responsibilities. This plan shall be made available to the Department on request.

7:28-2.11 Inspections

(a) All persons shall afford the Department an opportunity to inspect any source of radiation and the operation associated with the source of radiation as well as the facilities and premises where the source of radiation is being used or stored.

(b) Upon request of the Department all persons shall make available for inspection by the Department records kept pursuant to the rules in N.J.A.C. 7:28.

7:28-2.12 Tests

Upon request of the Department, all persons shall perform, and/or permit the Department to perform if it so desires, such tests as the Department deems appropriate or necessary for the administration of this chapter.

SUBCHAPTER 3. REGISTRATION OF IONIZING RADIATION-PRODUCING MACHINES AND RADIOACTIVE MATERIALS3. REGISTRATION OF IONIZING RADIATION-PRODUCING MACHINES AND RADIOACTIVE MATERIALS

7:28-3.1 Registration for possession of ionizing radiation-producing machines and radioactive by-product material, source material and special nuclear material

(a) Any person, manufacturer, dealer or State, county or local government shall register with the Department all radioactive by-product material, source material, special nuclear material and every ionizing radiation-producing machine possessed within the State of New Jersey except as exempted by N.J.A.C. 7:28-3.2.

(b) Any person, manufacturer, dealer or State, county or local government shall apply for such registration within 30 days after taking possession, custody or control of radioactive by-product material, source material, special nuclear material and ionizing radiation-producing machines on forms available from the Department.

(c) Any person, manufacturer, dealer or State, county or local government shall retain a copy of the registration at the facility for inspection by employees and the Department.

7:28-3.2 Exemptions from registration for possession of ionizing radiation-producing machines and radioactive by-product material, source material and special nuclear material

(a) Ionizing radiation-producing machines not being used in such a manner as to produce radiation, such as equipment in storage or on display, are exempt from registration. Machines that are operated while on display must meet the requirements of N.J.A.C. 7:28-3.1.

(b) Electrical equipment that is not primarily intended to produce radiation and that does not produce radiation greater than 0.5 millirem per hour at any readily accessible point five centimeters from its surface is exempt from registration. Production-testing facilities for such equipment shall not be exempt if any individual might receive a radiation dose exceeding the limits established in N.J.A.C. 7:28-6.2.

(c) Ionizing radiation-producing machines possessed, stored or used by agencies of the United States Government are exempt from registration.

(d) Those radioactive materials covered in specific and general state licenses issued by the Department in accordance with N.J.A.C. 7:28-4 are exempt from registration.

(e) Those radioactive materials contained in devices which are covered under general license issued by the United States Nuclear Regulatory Commission or have been granted an exemption from licensing requirements by the United States Nuclear Regulatory Commission are exempt from registration.

(f) Quantities of radioactive material equal to or less than those listed in N.J.A.C. 7:28-3.11 are exempt from registration requirements provided that no individual user of radioactive material shall have more than 10 such quantities of any material or materials at any one time.

7:28-3.3 Registration of ionizing radiation-producing machines

(a) Registration of ionizing radiation-producing machines shall pertain to each x-ray tube and its accompanying transformer, generator and control panel. If more than one x-ray tube operates off the same control panel, a separate registration is required for each tube.

(b) All registrations issued for ionizing radiation-producing machines shall expire on May 19 of each renewal year or shall expire one year from the date of initial application as determined by the Department. Registrations are renewable by the registrant for a period of one year upon payment of the fee provided in N.J.A.C. 7:28-3.12.

(c) Applications for new registrations for ionizing radiation producing machines will be accepted throughout the calendar year. The annual registration fee set forth in N.J.A.C. 7:28-3.12 shall be either prorated from the date the registration is issued until its expiration date on May 19 following the date of application, except that the Department may issue a registration for an additional year when an application is initially filed during the last three months of the registration year, or shall be assessed in full from the date of application until its expiration date one year later as determined by the Department.

7:28-3.4 Temporary registration of ionizing radiation-producing machines

(a) Any person, manufacturer, dealer or State, county or local government having temporary possession, custody or control of any ionizing radiation-producing machine for the purpose of replacing a registered machine that is out of service for a period longer than 60 days or for evaluation prior to purchase for a period longer than 60 days shall obtain a registration for temporary possession, custody or control of said machine.

(b) Application for temporary registration shall be submitted, on forms available from the Department, within 30 days after taking temporary possession, custody or control. No registration fee will be charged if the period of temporary possession, custody or control does not exceed 60 days. If the period exceeds 60 days, the annual registration fee for said machine set forth in N.J.A.C. 7:28-3.12 will be charged as of the date of application for the temporary registration.

(c) Within 30 days after relinquishment of temporary possession, custody or control of an ionizing radiation-producing machine, the registrant shall notify the Department in writing to terminate the temporary registration. The Department shall continue to charge a registration fee until a written notice of termination is received from the registrant.

7:28-3.5 Registration of radioactive by-product material, source material and special nuclear material

Any person having within his possession, custody or control any radioactive by-product material, source material or special nuclear material pursuant to a license issued by the United States Nuclear Regulatory Commission shall apply for and obtain a registration for possession, custody or control of the specified type(s) and amount(s) of such material as authorized by the license issued by the Nuclear Regulatory Commission. Application forms for the registration of radioactive material are available from the Department. When submitting an application, the applicant shall attach to the application a copy of the license issued by the Nuclear Regulatory Commission.

(b) A registrant does not have to apply for a new or amended registration for receipt of each shipment of a type of radioactive material for which it has a valid current registration provided that the total amount of such type of radioactive material in the registrant's possession, custody or control does not exceed the amount authorized in its registration for such type of material.

(c) Fees in the amounts indicated in N.J.A.C. 7:28-3.13 shall be paid for each initial registration application, each registration amendment and each annual registration renewal.

(d) Any registration issued for radioactive materials pursuant to this subchapter shall be valid for so long as the license issued by the United States Nuclear Regulatory Commission is in full force and effect.

7:28-3.6 Transfer of registration for possession of radioactive by-product material, source material, special nuclear material and ionizing radiation-producing machines

Registrations for possession of radioactive by-product material, source material, special nuclear material and ionizing radiation-producing machines are not transferable.

7:28-3.7 Amendments to registration of ionizing radiation-producing machines

(a) A registrant must notify the Department in writing within 30 days after any change in the following information on the application for registration of an ionizing radiation-producing machine:

1. Trade name;
2. X-ray tube capacity;
3. Type of housing;
4. Generator power;
5. Owner;
6. Co-owner;
7. Location of machine including address (number, street, city, zip code, county) and room number;
8. Machine category;
9. Manufacturer;
10. Control panel model number; and
11. Control console serial number.

7:28-3.8 Amendments to registration of radioactive by-product material, source material or special nuclear material

A registrant shall notify the Department in writing within 30 days of any change in the license issued by the Nuclear Regulatory Commission for possession, custody or control of any type of radioactive by-product material, source material or special nuclear material when there is a change in the type and/or quantity of such material or when there is a change in the designated licensed user(s) or radiation safety officer.

7:28-3.9 Sale, installation, relocation or disposal of ionizing radiation-producing machines

(a) Whenever a manufacturer or dealer sells, installs, relocates or disposes of an ionizing radiation-producing machine, said manufacturer, agent or dealer shall give written notification thereof to the Department within 30 days of such sale, installation, relocation or disposal. Said notification shall included the manufacturer, model and serial number of each component, name and address of the new owner(s), address of the relocated machine or details of the final disposition of the machine. Notification shall be submitted on a form available from the Department. The Department may accept the current form used by the United States Food and Drug Administration for Report of Assembly of a Diagnostic X-ray System if the Department determines that the information is complete and accurate.

(b) Whenever an owner sells, relocates or disposes of an ionizing radiation-producing machine, said owner shall:

1. Give written notification to the Department on forms available from the Department within 30 days of such sale, relocation or disposal;
2. Include the New Jersey registration number, manufacturer, model and serial number of each component;
3. Include the name and address of the new owner(s), and
4. Include the address of the relocated machine, or details of the final disposition of the machine; and
5. Be responsible for all fees until the written notification is received by the Department.

7:28-3.10 Denial of an application for registration, and suspension, modification, or revocation of registration of ionizing radiation-producing machines, radioactive by-product material, source material or special nuclear material

(a) The Department, in addition to any penalties authorized by the Act, may deny an application for registration or suspend, modify or revoke a registration of ionizing radiation-producing machines, radioactive by-product material, source material or special nuclear material by reason of amendments to the Act, adoption of rules, orders issued by the Department pursuant to said Act or if the applicant or registrant:

1. Fails to comply with any provisions of the Act or any rules promulgated pursuant thereto including the timely payment of registration fees;
2. Falsifies or makes misleading statements in the application for registration;
3. Falsifies or makes misleading statements in any documents which were utilized to obtain a registration;
4. Alters registration documents;
5. Falsifies required records;
6. Aids, abets, combines with, or conspires with any person for any purpose which will evade or be in violation of the provisions of the Act or any rules promulgated pursuant thereto; or
7. Allows a registration to be used by any person for any purpose which will evade or be in violation of the provisions of the Act or any rules promulgated pursuant thereto.

(b) Except as provided in N.J.S.A. 26:2D-12 in cases of emergency, no registration shall be denied, modified, suspended or revoked prior to a hearing conducted by the Office of Administrative Law pursuant to N.J.S.A. 52:14B-1 et seq., the Administrative Procedure Act, and N.J.A.C. 1:1-1 et

seq., the Uniform Administrative Practice Rules, on the basis of a Notice of Intent filed by the Department stating the grounds for denial, suspension, modification or revocation of a registration.

(c) The Department may terminate a registration upon request submitted by the registrant to the Department in writing.

7:28-3.11 Table of radioactive materials and quantities exempt from registration

(a) The following radioactive materials, in quantities less than or equal to those specified below, are exempt from registration:

#

Radioactive Material	Column A Not as a sealed source (microcuries)	Column B As a sealed source (microcuries)
Antimony (Sb 124)	1	10
Arsenic 76 (As 76)	10	10
Arsenic 77 (As 77)	10	10
Barium 140/+Lanthanum 140 (Ba 140/+La 140)	1	10
Beryllium (Be 7)	50	50
Cadmium 109/+Silver 109 (Cd 109/+Ag 109)	10	10
Calcium 45 (Ca 45)	10	10
Carbon 14 (C 14)	50	50
Cerium 144/+Praseodymium 144 (Ce 144/+Pr 144)	1	10
Cesium 137/+Barium 137 (Ce 137/+Ba 137)	1	10
Chlorine 36 (Cl 36)	1	10
Chromium 51 (Cr 51)	50	50
Cobalt 60 (Co 60)	1	10
Copper 64 (Cu 64)	50	50
Europium 154 (Eu 154)	1	10
Fluorine 18 (F 18)	50	50
Gallium 72 (Ga 72)	10	10
Germanium 71 (Ge 71)	50	50
Gold 198 (Au 198)	10	10
Gold 199 (Au 199)	10	10
Hydrogen 3 (Tritium H 3)	250	250
Indium 114 (In 114)	1	10
Iodine 131 (I 131)	10	10
Iridium 192 (Ir 192)	10	10
Iron 55 (Fe 55)	50	50
Iron 59 (Fe 59)	1	10
Lanthanum 140 (La 140)	10	10
Manganese 52 (Mn 52)	1	10
Manganese 56 (Mn 56)	50	50
Molybdenum 99 (Mo 99)	10	10
Nickel 59 (Ni 59)	1	10
Nickel 63 (Ni 63)	1	10
Niobium 95 (Nb 95)	10	10
Palladium 109 (Pd 109)	10	10
Palladium 103/+Rhodium 103 (Pd 103/+Rh 103)	50	50
Phosphorus 32 (P 32)	10	10
Polonium 210 (Po 210)	0.1	1
Potassium 42 (K 42)	10	10
Praseodymium 143 (Pr 143)	10	10

Promethium 147 (Pm 147)	10	10
Rhenium 186 (Re 186)	10	10
Rhodium 105 (Rh 105)	10	10
Rubidium 86 (Rb 86)	10	10
Ruthenium 106/+Rhodium 106 (Ru 106/+Rh 106)	1	10
Samarium 153 (Sm 153)	10	10
Scandium 46 (Sc 46)	1	10
Silver 105 (Ag 105)	1	10
Silver 111 (Ag 111)	10	10
Sodium 22 (Na 22)	10	10
Sodium 24 (Na 24)	10	10
Strontium 89 (Sr 89)	1	10
Strontium 90/+Yttrium 90 (Sr 90/+Y 90)	0.1	1
Sulfur 35 (S 35)	50	50
Tantalum 182 (Ta 182)	10	10
Technetium 96 (Tc 96)	1	10
Technitium 99 (Tc 99)	1	10
Tellurium 127 (Te 127)	10	10
Tellurium 129 (Te 129)	1	10
Thallium 204 (Tl 204)	50	50
Tin 113 (Sn 113)	10	10
Tungsten 185 (W 185)	10	10
Vanadium 48 (V 48)	1	10
Yttrium 90 (Y 90)	1	10
Yttrium 91 (Y 91)	1	10
Zinc 65 (Zn 65)	10	10
Beta and/or Gamma emitting radioactive material not listed above	1	10

7:28-3.12 Application and annual registration renewal fees for ionizing radiation-producing machines

*****TABLE AND RULES OMITTED*****

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7:28-3.13 Fees for registration of radioactive by-product material, source material and special nuclear material

*****TABLE AND RULES OMITTED*****

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SUBCHAPTER 4. LICENSING OF NATURALLY OCCURRING AND ACCELERATOR PRODUCED RADIOACTIVE MATERIALS 4. LICENSING OF NATURALLY OCCURRING AND ACCELERATOR PRODUCED RADIOACTIVE MATERIALS

7:28-4.1 License required for production, transfer, receipt, acquisition, ownership, possession or use of all naturally occurring and accelerator produced radioactive materials

(a) This subchapter shall apply to persons who produce, transfer, receive, acquire, own, possess or use any naturally occurring or accelerator produced radioactive materials in this State.

(b) No person shall produce, transfer, receive, acquire, own, possess or use any radioactive substance obtained from naturally occurring materials or produced by an accelerator unless authorized by a specific State license issued by the Department, a general State license as provided in N.J.A.C. 7:28-4.5, or an exemption as provided in N.J.A.C. 7:28-4.3.

Excepted from this provision are by product source materials and special nuclear materials.

7:28-4.2 Recognition of licenses from other jurisdictions

(a) Any person who possesses a specific license or equivalent licensing document issued by a Federal agency or any other state may, pursuant to such document, transport, receive, possess, or use the radioactive materials specified in such license within this State for a period not in excess of 20 days in any period of 12 consecutive months without obtaining a specific license from the Department provided that:

1. The license does not limit the activity to specified installations or locations;

2. The licensee notifies the Department in writing at least two days prior to the time that such radioactive material is brought into this State. Such notification shall indicate the location, period, and type of proposed possession and use within this State, and shall be accompanied by a copy of the pertinent licensing document. If in a specific case the two-day period would impose an undue hardship on the user, he may, upon application to the Department, obtain permission to proceed sooner;

3. The licensee complies with all the terms and conditions of the license;

4. The licensee provides such other information as the Department may request; and

(b) The Department may withdraw, limit or qualify its acceptance of such licenses issued by another agency, or any produce distributed pursuant to such licensing documents, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

7:28-4.3 Exemption from requirement for a license for production, transfer, receipt, acquisition, ownership, possession or use of all naturally occurring and accelerator produced radioactive materials

(a) Any person is exempt from the requirement for a license for the production, transfer, receipt, acquisition, ownership, possession or use of all naturally occurring and accelerator produced radioactive materials as follows:

1. The person is a plant or laboratory owned by or operated on behalf of a Federal agency;

2. The person is a common or contract carrier and is transporting or storing radioactive materials covered by N.J.A.C. 7:28-4.7 in the regular course of carriage for another, or storage incident thereto;

3. To the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing naturally occurring or accelerator produced radioactive substances in concentrations not in excess of those exempted in N.J.A.C. 7:28-4.3(b);

4. To the extent that such person receives, possesses, uses, transfers, owns or acquires luminous timepieces or parts thereof containing radium. However, any person who desires to apply radium to luminous timepieces or parts thereof is not exempt and must obtain a specific State license;

5. Naturally occurring radioactive materials of an equivalent specific radioactivity not exceeding that of natural potassium (10-9 curies per gram of potassium);

6. If the Department, upon request by an owner or on its own initiative with the approval of the Commission, grants a specific exemption from any requirements of this subchapter should it determine that such exemption is not likely to result in unnecessary radiation.

(b) The following concentrations of radioactive substances when obtained from naturally occurring materials or when produced by an accelerator are exempt from the requirement for a license for the production, transfer, receipt, acquisition, ownership or use of all naturally occurring and accelerator produced radioactive materials:

Element (Atomic Number)	Isotope uCi/cc/a	Gas Concentration uCi/cc/a/a	Liquid & Solid Concentrations
Beryllium (4)	Be 7	--	2 x 10-2
Cadmium (48)	Cd 109	--	2 x 10-3
Carbon (6)	C 14	1 x 10-6	8 x 10-3
Chromium (24)	Cr 51	--	2 x 10-2
Cobalt (27)	Co 57	--	5 x 10-3
Hydrogen (1)	H 3	5 x 10-6	3 x 10-2
Iron (26)	Fe 55	--	8 x 10-3
Manganese (25)	Mn 52	--	3 x 10-4
Manganese (25)	Mn 54	--	1 x 10-3
Tungsten (74)	W 181	--	4 x 10-3
Vanadium (23)	V 48	--	3 x 10-4
Zinc (30)	Zn 65	--	1 x 10-3
Beta and/or gamma emitting radioactive material not listed above with half life less than 3 years	--	1 x 10-10	1 x 10-6

*Values are given only for those materials normally used as gases.

**uCi/gm for solid

1. Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in this section, the value given is that of the parent isotope and takes into account the radioactivity of the daughters.

2. For purposes of N.J.A.C. 7:8-4.3(a)4, where a combination of isotopes is involved, the limit for the combination shall be computed as follows:

   i. Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in this section for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (unity).

Example:

$$\frac{\text{Prod. Conc. of Isotope A}}{\text{Exempt Conc. of Isotope A}} + \frac{\text{Prod. Conc. of Isotope B}}{\text{Exempt Conc. of Isotope B}} + \frac{\text{Prod. Conc. of Isotope C}}{\text{Exempt Conc. of Isotope C}} \leq 1$$

7:28-4.4 Types of licenses for production, transfer, receipt, acquisition, ownership, possession or use of all naturally occurring and accelerator produced radioactive materials

(a) General State licenses described in N.J.A.C. 7:28-4.5 are effective without the filing of an application with the Department or the issuance of licensing documents to particular persons.

(b) Specific State licenses are issued to named persons upon application filed pursuant to the requirements of this subchapter.

7:28-4.5 General licenses for the transfer, receipt, acquisition, ownership, possession or use of naturally occurring and accelerator produced radioactive materials and certain devices and equipment

(a) Any person who uses, transfers, receives, acquires, owns or possesses the following devices and equipment incorporating naturally occurring and/or accelerator produced radioactive material, when manufactured, tested and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the Department, or a specific license of a Federal agency or any other state, shall be deemed to have a general State license:

1. Devices designed for use as static eliminators and which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of Polonium 210 or 50 microcuries of Radium 226 per device;

2. Spark gap tubes and electronic tubes which contain radioactive material consisting of not more than one microcurie of Radium per tube;

3. Devices designed for ionizing of air and which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of Polonium 210 or 50 microcuries of Radium 226 per device.

(b) The devices described in (a) above shall not be transferred, abandoned or disposed of except by transfer to a person duly authorized to receive such device by a specific State license issued by the Department, a Federal agency, or any other state.

(c) The following quantities of radioactive substances, when obtained from naturally occurring materials or when produced by an accelerator, are generally licensed provided that no person shall at any one time possess or use more than a total of 10 such quantities:

Radioactive Material	Column A Not as a Sealed Source (microcuries)	Column B As a Sealed Source (microcuries)
Beryllium (Be-7)	50	50
Bismuth 207 (Bi-207)	1	10
Cadmium 109-Silver 109 (Cd 109/+Ag 109)	10	10
Cerium 141 (Ce-141)	1	10
Chromium 51 (Cr-51)	50	50
Cobalt 57 (Co-57)	20	20
Germanium 68 (Ge-68)	1	10
Iron 55 (Fe-55)	50	50
Manganese 52 (Mn-52)	1	10
Polonium 210 (Po-210)	0.1	1
Radium and daughters	0.1	1
Sodium 22 (Na-22)	10	10
Vanadium 48 (V-48)	1	10
Zinc 65 (Zn-65)	10	10
Beta and/or gamma emitting radioactive material not listed above	1	10

(d) There are no generally licensed quantities for alpha-emitting materials other than those set forth in N.J.A.C. 7:28-4.5(c).

(e) Any person who owns, receives, acquires, possesses or uses radioactive material when contained in a device designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition or for producing light or an ionized atmosphere, when such devices are manufactured in accordance with the specifications contained in a specific license authorizing distribution under a general license issued to the supplier by the Department, a Federal agency, or any other state, is deemed to have a general State license, provided that:

1. The device is labeled in accordance with the provisions of the specific license which authorizes the distribution of the devices;

2. The device bears a label containing the following or a substantially similar statement:

"This device contains radioactive material and has been manufactured for distribution as a generally licensed device pursuant to

_____
(identify appropriate section of the rules)

_____
(name of licensing agency and state)

License No._____by_____(name of supplier)

This device shall not be transferred, abandoned or disposed of except by transfer to a person duly authorized to receive such device by a specific license issued by the Department, a Federal agency, or any other state.

Removal of this label is prohibited."; and

3. The devices requiring special installation shall be installed on the premises of the general licensee by a person authorized to install the devices under a specific license issued to the installer by the Department, a Federal agency, or any other state.

(f) Persons who transfer, receive, acquire, own, possess or use items and quantities of radioactive materials set forth in N.J.A.C. 7:28-4.5(a) and (c) pursuant to a general State license shall not:

1. Effect an increase in the radioactivity of such scheduled items or quantities by adding other radioactive material thereto, by combining radioactive material from two or more such items or quantities, or by altering them in any other manner so as to increase the rate of radiation emission;

2. Administer or direct the adminstration of the scheduled items or quantities or any part thereof to a human being, either externally or internally, for any purpose, including, but not limited to, diagnostic, therapeutic and research purposes;

3. Add or direct the addition of the scheduled items or quantities or any part thereof to any food, beverage, cosmetic, drug or other product designed for ingestion or inhalation by, or application to, a human being; or

4. Include the scheduled items or quantities or any part thereof in any device, instrument, apparatus, including component parts and accessories intended for use in diagnosis, treatment or prevention of disease in human beings or animals or otherwise intended to

affect the structure or any function of the body of human beings or animals.

(g) Persons who receive, acquire, possess or use a device pursuant to a general license specified in N.J.A.C. 7:28-4.5(a):

1. Shall not transfer, abandon or dispose of the device except by transfer to a person duly authorized to receive such device by a specific license issued by the Department, a Federal agency, or any other state:

2. Shall assure that all labels affixed to the device at the time of receipt and bearing the statement, "Removal of this label is prohibited", are maintained thereon and shall comply with the instructions contained in such labels;

3. Shall have the device tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at intervals not to exceed six months except that devices containing only tritium need not be tested for any purpose and devices containing only krypton need not be tested for leakage;

4. Shall have the tests required by N.J.A.C. 7:28-4.5(g)3 and all other services involving the radioactive material, its shielding and containment, performed by the supplier or other person duly authorized by a specific license issued by the Department, a Federal agency, or any other state to manufacture, install or service such devices;

5. Shall maintain records of all tests performed on the devices as required under N.J.A.C. 7:28-4.5(g)3, including the dates and results of the tests and the names and addresses of the persons conducting the tests;

6. Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding or containment of the radioactive material or the on-off mechanism or indicator, shall immediately suspend operation of the device until it has been either:

   i. Repaired by a supplier, manufacturer, or other person holding a specific license issued by the Department, a Federal agency, or any other state to manufacture, install or service such devices; or

   ii. Disposed of by transfer to a person holding a specific license issued by the Department, a Federal agency, or any other state to receive the radioactive material contained in the device; and

7. Shall be exempt from the requirements of this subchapter, except the provisions of N.J.A.C. 7:28-4.4(a), 4.9, 4.14, 4.18, 8.2, 8.4, and 13.

7:28-4.6 Application for and renewal of specific State licenses for the transfer, receipt, acquisition, ownership, possession or use of naturally occurring and accelerator produced radioactive materials

(a) Upon approval of an initial or renewal application, a specific State license may be issued by the Department for a period of five years commencing on the date the license is issued.

(b) Application for specific State licenses and renewals shall be filed with the Department, on forms available from the Department.

(c) All applications shall contain the following signature and certification:

1. "I certify under penalty of law that the information provided in this document is true,

accurate and complete. I am aware that there are significant civil and criminal penalties for submitting false, inaccurate or incomplete information, including fines and/or imprisonment."

2. The certification shall be signed by the highest ranking corporate, partnership, or governmental officer or official at the facility or the individual for which or for whom the specific State license is requested.

(d) An application for a specific State license may include a request for a State license authorizing one or more activities.

(e) Subject to the provisions of N.J.A.C. 7:28-4.7 and 4.8, an application for a specific State license for any human use or uses of radioactive material specified in one or more of the Human Use activity Groups I to VI inclusive listed in N.J.A.C. 7:28-4.7(b) may be approved for all of the uses within the group or groups which include the use or uses specified in the application.

(f) Information included in the specific State license application will be incorporated in and made a part of the terms and conditions of such license by reference.

(g) All applicants for initial and renewal applications for specific State licenses shall complete the application in its entirety with no reference to previously filed documents. The Department may accept photocopies of previous relevant applications.

(h) No initial or renewal specific State licenses shall be issued unless the appropriate annual license fee required by N.J.A.C. 7:28-4.18 is paid.

(i) Except as provided in N.J.A.C. 7:28-4.20, applications and documents submitted to the Department will be made available for public inspection.

(j) Upon the request of the Department at any time after the filing of the original or renewal specific State license application, and before the expiration of the license, the applicant shall submit further information to enable the Department to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(k) All applications for license or amendment shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

(l) The Department may deny an application for a specific State license if the applicant:

1. Fails to comply with any provisions of the Act or any rules promulgated thereunder;
2. Falsifies or makes misleading statements in the application for license; or
3. Falsifies or makes misleading statements in any documents which were utilized to obtain a license.

7:28-4.7 General requirements for approval of an application for an initial specific State license or renewal of a specific State license for use of naturally occurring and accelerator produced materials

(a) If the Department determines that an applicant meets the requirements of this subchapter and the Act, it may issue an initial specific State license or renew a specific State license for non-human use of radioactive materials provided:

1. The applicant is qualified by reason of training and experience to use the radioactive material for the purpose requested in such manner as to protect health, minimize danger to life or property and prevent unnecessary radiation;

2. The applicant's proposed equipment, facilities and procedures are adequate to protect health, minimize danger to life or property and prevent unnecessary radiation; and

3. The applicant satisfies special requirements as may be applicable in N.J.A.C. 7:28-4.8.

(b) If the Department determines that an applicant meets the requirements of this subchapter and the Act, it may issue an initial specific State license or renew a specific State license for human use of radioactive materials for one or more of the following Human Use Groups of activities:

1. Group I: Use of prepared radiopharmaceuticals for certain diagnostic studies involving measurements of uptake, dilution and excretion. This group does not include imaging or localization studies;

2. Group II: Use of prepared radiopharmaceuticals for diagnostic imaging and localization studies;

3. Group III: Use of generators and reagent kits for the preparation and use of radiopharmaceuticals for certain diagnostic studies;

4. Group IV: Use of prepared radiopharmaceuticals for certain therapeutic uses that do not normally require hospitalization for purposes of radiation safety;

5. Group V: Use of prepared radiopharmaceuticals for certain therapeutic uses that normally require hospitalization for purposes of radiation safety; and

6. Group VI: Use of sources and devices containing radionuclides for certain medical uses.

(c) To qualify for an initial specific State license or renewal of a specific State license for human use of radioactive materials for any purpose described in Groups I through VI in (b), above the applicant must demonstrate qualification by reason of training and experience to use the radioactive material for the purpose requested and in such manner as to protect health, minimize danger to life or property, and prevent unnecessary radiation, by satisfying the training and experience requirements for the appropriate Human Use Group of activities as follows:

1. The training and experience must have been obtained within a five year period preceding the date of the application for an initial or renewal specific State license or must be supplemented by continuing education or experience. The original training and experience should have been received in a formal residency program in an accredited medical institution. Each applicant's training and experience are examined on a case-by-case basis. If an applicant wishes to use radiopharmaceuticals but does not have the training and experience described, the applicant may submit an application listing specific qualifications and these will be considered by the Department.

2. To qualify as adequately trained to use or directly supervise the use of radioactive material listed in Human Use Groups I, II, and/or III, an applicant shall have all the training and experience specified in (c)2i, ii and iii below;

Two hundred hours training in basic radioisotope handling techniques applicable to the use of unsealed sources. This training shall consist of lectures, laboratory sessions, discussion groups, or supervised experience in a nuclear medicine laboratory (that is, on-the-job training in a formalized training program) in the following areas and for the specific hours of class, laboratory or clinical experience:

(1) Radiation physics and instrumentation (100 hours);
(2) Radiation protection (30 hours);
(3) Mathematics pertaining to the use and measurement of radioactivity (20 hours);
(4) Radiation biology (20 hours); and
(5) Radiopharmaceutical chemistry (30 hours);

ii. Five hundred hours of experience with the types and quantities of radioactive material for which the application is being made. For authorization of Human Use Group III (generators and reagent kits), this experience shall include personal participation in five elution procedures, including testing of eluate, and in five procedures to prepare radiopharmaceuticals from Human Use Group III reagent kits; and

iii. Five hundred hours of supervised clinical training in an institutional nuclear medicine program. The clinical training shall cover all appropriate types of diagnostic procedures and shall include:

(1) Supervise examination of patients to determine the suitability for radioisotope diagnosis and recommendation on dosage to be prescribed;
(2) Collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurement, and plotting data;
(3) Follow-up of patients when required; and
(4) Study and discussion with preceptor of case histories to establish most appropriate diagnostic procedures, limitation, contraindication, etc.

3. The requirements specified in (c)2i, ii and iii above may be satisfied concurrently in a three month training program if all three areas are integrated into the program.

4. Certification by the American Board of Nuclear Medicine, or the American Board of Radiology in Diagnostic Radiology with Special Competence in Nuclear Radiology, will be accepted as evidence that an applicant has had adequate training and experience to use Human Use Groups I, II, and III as specified in (c)2i, ii and iii above.

5. An applicant who wishes to be authorized for only one or two specific diagnostic procedures shall have training in basic radioisotope handling techniques and clinical procedures commensurate with the procedures and quantities of radioactive material being requested. Such requests will be examined on a case-by-case basis by the Department.

6. To qualify as adequately trained to use or directly supervise the use of radioactive material listed in Groups IV and/or V, an applicant shall have:

i. Eighty hours training in basic radioisotope handling techniques applicable to the use of unsealed sources for therapy procedures, consisting of lectures, laboratory sessions, discussion groups or supervised experience in the following areas and for the following specific hours:

(1) Radiation physics and instrumentation (25 hours);
(2) Radiation protection (25 hours);
(3) Mathematics pertaining to the use and measurement of radioactivity (10 hours); and
(4) Radiation biology (20 hours);

7. To qualify as adequately trained to use or directly supervise the use of radioactive material listed in Group VI an applicant shall have:

i. Two hundred hours training in basic radioisotope handling techniques applicable to the use of sealed sources for therapy procedures, consisting of lectures, laboratory sessions, discussion groups, or supervised experience in the following areas and for the following specified hours:

(1) Radiation physics and instrumentation (110 hours);
(2) Radiation protection (40 hours);
(3) Mathematics pertaining to the use and measurements of radioactivity (25 hours); and
(4) Radiation biology (25 hours);

ii. Five hundred hours experience with the types and quantities of radioactive material for which the application is made;

iii. Clinical training in Group VI procedures consisting of active practice in therapeutic radiology with a minimum of three years experience of which at least one year shall have been spent in a formal training program accredited by the Residency Review Committee of Radiology and the Liaison Committee on Graduate Medical Education; and

iv. Evidence of certification by the American Board of Radiology in Radiology or Therapeutic Radiology, certification as a British "Fellow of the Faculty of Radiology" (FFR) or "Fellow of the Royal College of Radiology" (FRCR), or Canadian certification from the Royal College of Physicians and Surgeons (RCPS) in therapeutic radiology may be submitted in lieu of the training required in (c)7i and iii above.

8. In addition to the training required by (c)7 above, an applicant for a license for Human Use Group VI activities shall demonstrate that its proposed equipment, facilities and procedures are adequate to protect health, minimize danger to life or property and prevent unnecessary radiation; and

9. An applicant for a license for Human Use Group VI activities shall satisfy special requirements as may be applicable in N.J.A.C. 7:28-4.8.

7:28-4.8 Special requirements for approval of an application for an initial specific State license or renewal of a specific State license for use of naturally occurring and accelerator produced radioactive materials

(a) If the Department determines that an applicant meets the requirements of this subchapter and the Act, an initial specific State license or renewal of a specific State license may be issued for human use of radioactive materials by an institution provided:

1. The applicant satisfies the general requirements for approval of specific State license applications in N.J.A.C. 7:28-4.7;

2. The applicant has appointed a medical isotopes committee to evaluate all proposals for research, diagnosis, and therapeutic use of radioactive material within that institution. Membership of the committee shall include one authorized user for each type of use permitted by the license, the radiation safety officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a radiation safety officer;

3. The applicant possesses adequate facilities for the clinical care of patients;

4. The physician(s) designated on the application as the individual user(s) has considerable pertinent training and experience in the use, handling and administration of radioactive material and, where applicable, the clinical management of radioactive patients; and

5. If the application is for a specific State license to use unspecified quantities of multiple types of radioactive materials, the applicant's staff has had substantial pertinent experience in using a variety of radioactive materials for various human uses.

(b) If the Department determines that an applicant meets the requirements of this subchapter and the Act, an initial specific State license or renewal of a specific State license may be issued for human use of radioactive materials by a physician or dentist provided:

1. The applicant satisfies the general requirements for approval of specific State license applications in N.J.A.C. 7:28-4.7;

2. The applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patient whenever it is advisable; and

3. The applicant has had extensive training and supervised experience in the proposed use, the handling and administration of radioisotopes and, where applicable, the clinical management of radioactive patients. The applicant shall furnish suitable evidence of such experience with his application. A statement from the institution where the applicant acquired the training and experience, indicating its amount and nature, may be submitted as evidence of such experience.

(c) If the Department determines that an applicant meets the requirements of this subchapter and the Act, an initial specific State license or renewal of a specific State license may be issued for human use of a sealed source of radioactive materials provided:

1. The applicant satisfies the general requirements for approval of specific State license applications in N.J.A.C. 7:28-4.7;

2. The applicant or, if the application is made by an institution, the individual user(s) has specialized training in therapeutic use of the radioactive device considered or has experience equivalent to such training; and

3. The individual user is a physician or dentist.

(d) If the Department determines that an applicant meets the requirements of this subchapter and the Act, an initial specific State license or renewal of a specific State license may be issued for use of multiple quantities or types of radioactive material in research and development provided:

1. The applicant satisfies the general requirements for approval of specific State license applications in N.J.A.C. 7:28-4.7;

2. The applicant's staff has had substantial training and experience with a variety of radioisotopes for various research and development uses;

3. The applicant has established an isotope committee, composed of a radiological safety officer, a representative of management and one or more persons trained or experienced in the safe use of radioactive materials, which will review and approve or disapprove proposals for use of radioactive materials in the advance of purchase of such materials; and

4. The applicant has appointed a radiological safety officer who shall be responsible for rendering advice and assistance on radiological safety.

(e) If the Department determines that an applicant meets the requirements of this subchapter and the Act, an initial specific State license or renewal of a specific State license may be issued for use of multiple quantities or types of radioactive material in processing for distribution to other authorized persons provided:

1. The applicant satisfies the general requirements for approval of specific State license application in N.J.A.C. 7:28-4.7;

2. The applicant's staff has had training and experience in the processing and distribution of a variety of radioisotopes; and

3. The applicant has appointed a radiological safety officer who shall be responsible for rendering advice and assistance on radiological safety.

(f) If the Department determines that an applicant meets the requirements of this subchapter and the Act, an initial specific State license or renewal of a specific State license may be issued to distribute certain devices to persons generally licensed under N.J.A.C. 7:28-4.5(a) and

(e) provided:

1. The applicant satisfies the general requirements for approval of specific State license applications in N.J.A.C. 7:28-4.7;

2. The applicant submits sufficient information relating to the design, manufacturer prototype testing, quality control procedures, labeling, proposed uses and potential hazards of the device to provide reasonable assurance that:

i. The radioactive material contained in the device cannot be easily removed from the device;

ii. No person possessing, using, transporting or exposed to the device will receive a radiation dose to a major portion of his body in excess of 0.5 rem in any one year under ordinary circumstances of use;

iii. The device can be safely operated by persons not having training in radiological protection; and

iv. The radioactive material within the device would not be accessible to unauthorized persons; and

3. In describing the label or lables and contents thereon to be affixed to the device, the applicant shall separately indicate those instructions and precautions which are necessary to assure safe operation of the device. Such instructions and precautions shall be contained on labels as described in N.J.A.C. 7:28-4.5(e).

(g) If the Department determines that an applicant meets the requirements of this subchapter and the Act, an initial specific State license or renewal of a specific State license may be issued for use of a sealed source or sources of radioactive materials in industrial and nonmedical radiography provided:

1. The applicant satisfies the general requirements for approval of specific State license applications in N.J.A.C. 7:28-4.7;

2. The applicant has an adequate program for training radiographers and radiographers' assistants and submits to the Department a schedule or description of such program which specifies the following:

    i. Initial training;
    ii. Periodic training;
    iii. On-the-job training;
    iv. Means to be used by the licensee to determine the radiographer's knowledge and understanding of and ability to comply with the requirements of this subchapter, the specific licensing requirements, and the operating and emergency instructions of the applicant; and
    v. Means to be used by the licensee to determine the radiographer's assistant's knowledge and understanding of and ability to comply with the operating and emergency procedures of the applicant;

3. The applicant has established and submitted to the Department satisfactory written operating and emergency instructions as prescribed by N.J.A.C. 7:28-17;

4. The applicant will have an adequate internal inspection system, or other management control, providing assurance that the requirements of this chapter, the specific State license provisions, and the applicant's operating and emergency instructions are followed by radiographers and radiographers' assistants;

5. The applicant submits a description of its overall organizational structure pertaining to the radiography program, including specified delegation of authority and responsibility for operation of the program; and

6. The applicant who desires to conduct his own leak tests has established adequate procedures to be followed in leak testing sealed sources for possible leakage and contamination and submits to the Department a description of such procedures, including:

    i. Instrumentation to be used;
    ii. Method of performing test (for example, points on equipment from where wipe samples will be taken and method of obtaining the wipe sample); and
    iii. Pertinent experience of the person who will perform the test.

(h) If the Department determines that an applicant meets the requirements of this subchapter and the Act, an initial specific State license or renewal of a specific State license will be issued to transfer, possess, or control products or materials containing exempt concentrations of radioactive material specified in N.J.A.C. 7:28-4.3(b) which the transferor has introduced into the product or material provided:

1. The applicant satisfies the general requirements for approval of specific State license applications in N.J.A.C. 7:28-4.7;

2. The applicant submits:

    i. A description of the product or material into which the radioactive material will be introduced;

ii. The intended use of the radioactive material and the product into which it is introduced;
iii. The method of introduction;
iv. The initial concentration of the radioactive material in the product or material;
v. The control methods to assure that no more than the specified concentration is introduced into the product or material;
vi. The estimated time interval between introduction and transfer of the product or material; and
vii. The estimated concentration of the radioisotope in the product or material at the time of proposed transfer by the applicant;

3. The applicant provides:

i. Reasonable assurance that the concentrations of the radioactive material at the time of transfer will not exceed the exempt concentrations listed in N.J.A.C. 7:28-4.3(b);
ii. That reconcentration of the radioactive material in concentrations exceeding those exempted under N.J.A.C. 7:28-4.3(b) is not likely;
iii. That the product or material is not likely to be inhaled or ingested; and
iv. That use of the lower concentration(s) is not feasible; and

4. Within 30 days subsequent to the end of the reporting period, each licensee shall file an annual report with the Department describing the kinds and quantities of products transferred, the concentration of radioactive material contained and the quantity of radioactive material transferred during the reporting period which shall be the 12 month period ending June 30 of each calendar year.

(i) If the Department determines that an applicant meets the requirements of this subchapter and the Act, an initial specific State license or renewal of a specific State license may be issued to distribute certain devices to persons specifically licensed under N.J.A.C. 7:28-4.7 provided:

1. The applicant satisfies the general requirements for approval of specific State license applications in N.J.A.C. 7:28-4.7;

2. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling, proposed uses and potential hazards of the device to provide reasonable assurance that:

i. The radioactive material contained in the device cannot be easily removed;
ii. The device can be safely operated by persons having trained in radiological protection; and
iii. The radioactive material within the device would not be accessible to unauthorized persons; and

3. Each device distributed as authorized by such license is to bear a label containing the following or substantially similar statements:

i. “Caution Radioactive Materials”;
ii. The isotope name;
iii. The isotope quantity and date; and
iv. The following statement:

“This device contains radioactive material and has been manufactured for distribution as a specifically licensed device pursuant to

_____
(identify appropriate section of the regulation)
_____
(name of licensing agency and state)
License No._____by_____(name of supplier)
Disposal of this device shall conform to the requirements
listed in N.J.A.C. 7:28-4.5(g)6ii of the Radiation Protection Code
Removal of this label is prohibited."

7:28-4.9 Terms and conditions of general and specific Statelicenses

(a) Each State license issued pursuant to this subchapter shall be subject to all the provisions of the Act, now or hereafter in effect, and to this chapter and orders of the Department.

(b) No license to possess or utilize radioactive material pursuant to this subchapter shall be transferred or assigned.

(c) Each person licensed by the Department pursuant to this subchapter shall confine his/her possession and use of radioactive material to the locations and purposes authorized by such license, and shall not use or permit the use of radioactive materials contrary to the applicable requirements of this chapter. Persons licensed under the provisions of this subchapter may transfer radioactive material within the State only to the persons licensed to receive such material or as otherwise authorized by the Department in writing.

(d) The Department may incorporate in any State license at the time of issuance, or thereafter, all such additional requirements and conditions with respect to the licensee's receipt, possession, use or transfer of radioactive material as it deems appropriate or necessary in order to assure compliance with this chapter and the Act.

(e) Each licensee authorized under N.J.A.C. 7:28-4.8(f) to distribute certain devices to generally licensed persons shall:

1. Report to the Department all transfers of such devices to persons in New Jersey generally licensed under N.J.A.C. 7:28-4.5(a) and (c). Such report shall identify each general licensee by name and address, the type and number of device(s) transferred, and the quantity and kind of radioactive material contained in each device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to generally licensed persons; and

2. Furnish to each general licensee to whom such device is transferred a copy of N.J.A.C. 7:28-4.5(a), (e) and (g), 8.2 and 8.4.

(f) Each licensee authorized under N.J.A.C. 7:28-4.8(i) to distribute certain devices to specifically licensed persons shall:

1. Report to the Department all transfers of such devices to persons in New Jersey specifically licensed under N.J.A.C. 7:28-4.7 and 4.8. Such report shall identify each specific licensee by name and address, the type and number of device(s) transferred, and the quantity and kind of radioactive material contained each device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to specifically licensed persons.

7:28-4.10 Expiration of specific State license

Except as provided in N.J.A.C. 7:28-4.11, each specific State license shall expire at 12:01 A.M. of the day, in the month and year stated in the license.

7:28-4.11 Status of specific State licenses pending renewal

In any case in which a licensee has filed a complete application in proper form for renewal of a specific State license not less than 30 days prior to expiration of the existing license, such license and all its existing conditions shall not expire until the Department has acted upon the application.

7:28-4.12 Amendment of a specific State license at request of licensee

(a) Applications for amendment of a specific State license shall be filed in accordance with N.J.A.C. 7:28-4.6 and shall specify the amendment desired and the grounds for such amendment.

(b) The Department will evaluate only amendment applications submitted by personnel authorized by the licensee.

(c) The applicant for an amended specific State license shall not engage in the activities for which an amendment has been requested until approval has been granted by the Department.

7:28-4.13 Records

All persons licensed pursuant to this subchapter shall keep records in accordance with N.J.A.C. 7:28-8.

7:28-4.14 Inspections

(a) All licensees shall allow the Department or its agents to inspect radioactive material and the facilities and premises where radioactive material is used or stored.

(b) No person shall prevent, prohibit, obstruct, hinder, delay or interfere with personnel of this Department or its agents in performing their duties.

(c) Upon request by the Department, or its agents licensees shall make available for inspection by the Department records kept pursuant to this chapter.

7:28-4.15 Tests

(a) At the request of the Department or its agents, each licensee shall perform, or allow the Department to perform if the Department so desires, such tests as the Department deems appropriate or necessary for the administration of this subchapter, including tests of the following:

1. Radioactive material;
2. Facilities where radioactive material is utilized or stored;
3. Radiation detection and monitoring instruments; and
4. Equipment and devices used in connection with the utilization or storage of radioactive material.

7:28-4.16 Modification, revocation, suspension, and termination of general and specific State licenses

(a) Each general State license shall be subject to modification, suspension or revocation by reason of amendments to the Act, adoption of rules by the Commission or the Department, orders issued by the Department pursuant to authority of the Act, or for violation or failure to observe any of the terms and provisions of the Act, license or any rule of the Commission or the Department, or order of the Department.

(b) Each specific State license shall be subject to modification, suspension or revocation by reason of:

1. Amendments to the Act;
2. Adoption of rules by the Commission;
3. Orders issued by the Department pursuant to the authority of the Act;
4. Conditions revealed by the application for a specific State license or statement of fact or any report, records or inspection or other means which would warrant the Department to refuse to grant a specific State license on an original application;
5. Violation of or failure to observe any of the terms and provisions of the Act or the license, or any rule of the Commission or Department or order of the Department;
6. Falsification or misleading statements in any license application;
7. Alteration of licensing document;
8. Falsification of required records; or
9. Failure to make timely payment of licensing fees.

(c) If a specific State license is not to be renewed or if a licensee requests a termination of its license, the licensee shall furnish to the Department, prior to the expiration date of the license, close-out surveys and/or wipe tests of the facility and a disposition certificate attestng to the disposal of radioactive material.

7:28-4.17 Requests for an adjudicatory hearing

(a) When the Department denies an initial application for or renewal of a specific State license, or determines to modify, revoke, suspend or terminate a general or specific State license, the Department shall send a notice of decision to the applicant or licensee by certified mail return receipt requested. The notice shall advise the applicant or licensee of the right to request a contested case hearing pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and the New Jersey Uniform Administrative Procedure Rules, N.J.A.C. 1:1-1 et seq. The notice shall include the following information:

1. Where and whom hearing requests should be sent;
2. The deadline by which hearing requests must be submitted;
3. The information that is required to be in the hearing request under (c) below; and
4. The requirements for requesting a stay under N.J.A.C. 7:28-4.18.

(b) All requests for a contested case hearing must be received by the Department within 30 calendar days of the date upon which the notice of decision was received.

(c) All requests for a contested case hearing shall be submitted in writing to the Department and shall contain:

1. The name, address and telephone number of the person making such request;

2. A statement of the legal authority and jurisdiction under which the request for a hearing is made;

3. A brief and clear statement of specific facts describing the Department decision appealed from as well as the nature and scope of the interest of the requestor in such decision; and

4. A statement of all facts alleged to be at issue and their relevance to the Department decision for which a hearing is requested. Any legal issues, associated with the alleged facts at issue, must also be included.

(d) The Department shall determine whether any request for a contested case hearing should be granted. In making such determination, the Department shall evaluate the request to determine

whether a contested case, as defined by the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., exists and whether there are issues of fact which, if assumed to be true, might change the Department's decision. Where only issues of law are raised by a request for a hearing, the request will be denied. Denial by the Department of a request for a contested case hearing shall constitute the final decision of the Department for the purposes of judicial appeal.

7:28-4.18 Requirements governing requests for stay of the effective date of the Department decision for which an adjudicatory hearing is requested

(a) The Department may grant a stay of the effective date of a decision to deny, modify, revoke or suspend any license. The applicant for such a stay must submit evidence that one of the following circumstances exist:

1. The granting of such stay is required as a constitutional or statutory right; or

2. The potential impact on public health, safety, welfare or the environment which might result from a decision to grant a stay is greatly outweighed by immediate, irreparable injury to the specific party requesting such stay.

(b) The decision to grant a contested case hearing request shall not automatically result in a stay of the Department action appealed from absent an express decision to stay such action by the Director. The burden shall be upon the party requesting a hearing to explicitly request a stay of action within the same document as well as to disclose reasons why such stay should be granted.

(c) Department decisions are effective, according to their terms, unless stayed by the Department in writing, upon receipt of written request pursuant to this section.

(d) Written requests for a stay of the effective date of the Department's decision must be made to the Department within 30 calendar days of the date upon which the notice of decision was received.

(e) Any stay that is granted by the Department shall be temporary and in no case shall it extend beyond the date of the Department's final decision of the contested case.

(f) Determinations made pursuant to this section shall be made in a writing mailed to the specific party making such request.

7:28-4.19 Specific State license fee schedule for the production, transfer, receipt, acquisition, ownership, possession or use of naturally occurring or accelerator produced radioactive material

(a) The specific State license fee schedule for the production, transfer, receipt, acquisition, ownership, possession or use of naturally occurring or accelerator produced radioactive materials is as follows:

****FEE SCHEDULE OMITTED****

(b) All licensees shall pay the fees set forth in (a) above by check payable to "Treasurer, State of New Jersey" prior to August 1 of each year.

1. In the event that the fees are paid after August 1, a delinquency fee equal to one-half of the annual license fee will be imposed. Failure to pay an annual license fee including any accrued delinquency fees for longer than 90 days shall constitute grounds for suspension or revocation of the license pursuant to N.J.A.C. 7:28-4.16.
2. The annual license fee shall be mailed to:

State of New Jersey

Department of Environmental Protection
Board of Revenue
428 East State Street
Trenton, New jersey 08625-0402

(c) Facilities for which multiple license categories apply shall be charged the sum of the fees for each of the applicable categories.

(d) The term "doses per year" when used in (a) above means the number of doses of radioactive materials within a category that are administered during the period July 1 to June 30.

(e) The term "human use group" when used in (a) above includes the use oc radioactiver material for calibration and quality control procedures as well as the administration of radioactive materials to humans.

7:28-4.20 Confidentiality claims

(a) Any applicant required to submit any information pursuant to the Act or this chapter which in the applicant's opinion constitutes trade secrets, proprietary information or information related to national security, may assert a confidentiality claim by following the procedures set forth in this subchapter.

(b) Any applicant submitting any information to the Department and asserting a confidentiality claim covering any information contained therein shall submit two documents to the Department. One shall contain all the information required by the Act or this chapter including any information which the applicant alleges to be entitled to confidential treatment. The second shall be identical to the first except that it shall contain no information which the applicant alleges to be entitled to confidential treatment. The second can be a photocopy of the first, with the allegedly confidential material blacked out.

(c) The top of each page of the first submission containing the information which the applicant alleges to be entitled to confidential treatment shall display the heading "CONFIDENTIAL" in bold type, or stamp.

(d) All parts of the text of the first submission which the applicant alleges to be entitled to confidential treatment shall be underscored or highlighted in a clearly identifiable manner. This manner of marking confidential information shall be such that both the allegedly confidential information and the underscoring or highlighting is reproducible on photocopying machines.

(e) The first submission, containing the information which the applicant alleges to be entitled to confidential treatment, shall be sealed in an envelope which shall display the word "CONFIDENTIAL" in bold type or stamp on both sides. This envelope, together with the second, non-confidential submission (which may or may not be enclosed in a separate envelope, at the option of the applicant), shall be enclosed in another envelope for transmittal to the Department. The outer envelope shall bear no marking indicating the confidential nature of the contents.

(f) To ensure proper delivery, the complete package should be sent by certified mail, return receipt requested, or by other means which will allow verification of receipt. Ordinary mail may be used, but the Department will assume no responsibility for packages until they are actually received.

7:28-4.21 Access to information; non-disclosure

(a) Until such time as a final confidentiality determination has been made, access to any information

for which a confidentiality claim has been made will be limited to Department employees whose activities necessitate such access and as provided at N.J.A.C. 7:28-4.24 and 4.26.

(b) No disclosure of information for which a confidentiality claim has been asserted shall be made to any other persons except as provided in this subchapter.

(c) Nothing in this section shall be construed as prohibiting the incorporation of confidential information into cumulations of data subject to disclosure as public records, provided that such disclosure is not in a form that would foreseeably allow persons, not otherwise having knowledge of such confidential information, to deduce from it the confidential information or the identity of the owner or operator who supplied it to the Department.

7:28-4.22 Confidentiality determinations

(a) Information for which a confidentiality claim has been asserted will be treated by the Department as entitled to confidential treatment, unless the Department determines that the information is not entitled to confidential treatment as provided in this section and N.J.A.C. 7:28-4.23.

(b) The Department shall act upon a confidentiality claim and determine whether information is or is not entitled to confidential treatment whenever the Department:

1. Receives a request under N.J.S.A. 47:1A-1 et seq. to inspect or copy such information; or
2. Desires to determine whether information in its possession is entitled to confidential treatment; or
3. Desires for any reason in the public interest to disclose the information to persons not authorized by this subchapter to have access to confidential information.

(c) The Department shall make the initial determination whether information is or is not entitled to confidential treatment.

1. If the Department determines that information is not entitled to confidential treatment, it shall so notify the applicant who submitted the information.

2. The notice required under this subsection shall be sent by certified mail, return receipt requested and shall state the reasons for the Department's initial determination.

3. An applicant who wishes to contest a determination by the Department shall, within 30 days of notification of the determination, submit evidence to support the applicant's contention that the Department's initial determination was incorrect. The evidence may include, but need not be limited to, a statement indicating:

i. The period of time for which confidential treatment is desired by the applicant (for example, until a certain date, until the occurrence of a specified event, or permanently);

ii. The measures taken by the applicant to guard against undesired disclosure of the information to others;

iii. The extent to which the information has been disclosed to others, and the precautions taken in connection therewith; and

iv. The extent of which disclosure of the information would result in substantial damage to the applicant, including a description of the damage, an explanation of why the damage would be substantial, and an explanation of the causal relationship between disclosure and the damage.

4. Failure of an applicant to furnish timely comments or exceptions waives the applicant's confidentiality claim.

5. The applicant may assert a confidentiality claim to any information submitted to the Department by an applicant as part of its comments pursuant to (c)4 above.

6. The Department may extend the time limit for submitting comments pursuant to (c)4 above for good cause shown by the applicant and upon receipt of a request in writing.

(d) After receiving the evidence, the Department shall review its initial determination and make a final determination.

1. If, after review, the Department determines that the information is not entitled to confidential treatment, the Department shall so notify the applicant by certified mail, return receipt requested. The notice shall state the basis for the determination, that it constitutes final agency action concerning the confidentiality claim, and that the Department shall make the information available to the public on the 14th day following receipt by the applicant of the written notice.

2. If, after review, the determination is made that information is entitled to confidential treatment, the information shall not be disclosed, except as otherwise provided by this subchapter. The applicant shall be notified of the Department's determination by certified mail, return receipt requested. The notice shall state the basis for the determination and that it constitutes final agency action.

7:28-4.23 Substantive criteria for use in confidentiality determinations

(a) When the applicant satisfies each of the following substantive criteria, the Department shall determine that the information for which a confidentiality claim has been asserted is confidential:

1. The applicant has asserted a confidentiality claim which has not expired by its terms, been waived or withdrawn;

2. The applicant has shown that reasonable measures have been taken to protect the confidentiality of the information and that the applicant intends to continue to take such measures;

3. The information is not, and has not been, available or otherwise disclosed to other persons without the applicant's consent (other than by subpoena or by discovery based on a showing of special need in a judicial or quasi-judicial proceeding, as long as the information has not become available to persons not involved in the proceeding);

4. No statute specifically requires disclosure of the information; and

5. The applicant has shown that disclosure of the information would be likely to cause substantial damage to its competitive position.

7:28-4.24 Disclosure of confidential information to other public agencies

(a) The Department may disclose confidential information to persons other than Department employees only as provided in this section or N.J.A.C. 7:28-4.25.

(b) The Department may disclose confidential information to any other State agency or to a Federal

agency if:

1. The Department receives a written request for disclosure of the information from a duly authorized officer or employee of the other agency;

2. The request sets forth the official purpose for which the information is needed;

3. The Department notifies the other agency of the Department's determination that the information is entitled to confidential treatment, or of any unresolved confidentiality claim covering the information;

4. The other State or Federal agency has first furnished to the Department a written formal legal opinion from the agency's chief legal officer or counsel stating that under applicable law the agency has the authority to compel the person who submitted the information to the Department to disclose such information to the other agency; and

5. The other agency agrees not to disclose the information further unless:

   i. The other agency has statutory authority both to compel production of the information and to make the proposed disclosure; or

   ii. The other agency has obtained the consent of the affected owner or operator to the proposed disclosure; and

6. The other agency has adopted regulations or operates under statutory authority that will allow it to preserve confidential information from unauthorized disclosure.

(c) Except as otherwise provided at N.J.A.C. 7:28-4.25, the Department shall notify in writing the applicant who supplied the confidential information of:

1. Its disclosure to another agency;
2. The date on which disclosure was made;
3. The name of the agency to which disclosed; and
4. A description of the information disclosed.

7:28-4.25 Disclosure by consent

(a) The Department may disclose any confidential information to any person if it has obtained the written consent of the applicant to such disclosure.

(b) The giving of consent by an applicant to disclose shall not be deemed to waive a confidentiality claim with regard to further disclosures unless the authorized disclosure is of such a nature as to make the disclosed information accessible to the general public.

7:28:4.26 Disclosure based on imminent and substantial danger

(a) Upon a finding that disclosure of confidential information would serve to alleviate an imminent and substantial danger to public health and the environment, the Department may:

1. Prescribe and make known to the applicant such shorter comment period (N.J.A.C. 7:28-4.22(c)4, post-determination waiting period (N.J.A.C. 7:28-4.22(d)1), or both, as it finds necessary under the circumstances; or

2. Disclose confidential information to any person whose role in alleviating the danger to

public health and the environment necessitates that disclosure. Any such disclosure shall be limited to information necessary to enable the person to whom it is disclosed to carry out the activities in alleviating the danger.

(b) Any disclosure made pursuant to this section shall not be deemed a waiver of a confidentiality claim, nor shall it of itself be grounds for any determination that information is no longer entitled to confidential treatment.

7:28-4.27 Security procedures

(a) Submissions to the Department pursuant to the Act and this chapter will be opened only by persons authorized by the Department engaged in administering the Act and this chapter.

(b) Only those Department employees whose activities necessitate access to information for which a confidentiality claim has been made, shall open any envelope which is marked "CONFIDENTIAL".

(c) All submissions entitled to confidential treatment as determined at N.J.A.C. 7:28-4.22 shall be stored by the Department only in locked cabinets.

(d) Any record made or maintained by Department employees which contains confidential information shall contain appropriate indicators identifying the confidential information.

7:28-4.28 Wrongful access or disclosure; penalties

(a) A person shall not disclose, seek access to, obtain or have possession of any confidential information obtained pursuant to the Act or this chapter, except as authorized by this subchapter.

(b) Every Department employee who has custody or possession of confidential information shall take appropriate measures to safeguard such information and to protect against its improper disclosure.

(c) A Department employee shall not disclose, or use for his or her private gain or advantage, any information which came into his or her possession, or to which he or she gained access, by virtue of his or her official position of employment or contractual relationship with the Department.

(d) If the Department finds that any person has violated provisions of this subchapter, it may:

1. Commence a civil action in Superior Court for a restraining order and an injunction barring that person from further disclosing confidential information.

2. Pursue any other remedy available by law.

(e) In addition to any other penalty that may be sought by the Department, violation of this subchapter by a Department employee shall constitute grounds for dismissal, suspension, fine or other adverse personnel action.

(f) Use of any of the remedies specified under this section shall not preclude the use of any other remedy.

SUBCHAPTER 5. CONTROLLED AREAS5. CONTROLLED AREAS

7:28-5.1 Areas which must be controlled

(a) Except as provided in (b) below, every area in which there is any reasonable possibility of an

occupant receiving an exposure dose from radiation and radioactive material more than the dose specified in N.J.A.C. 7:28-6 for radiation levels outside a controlled area shall be set apart as a controlled area by any person having possession, custody or control of any ionizing radiation-producing machine and/or radioactive material.

(b) All outgoing or incoming shipments of radioactive material shall be transported in conformance with N.J.A.C. 7:28-12 pertaining to transportation and all pertinent U.S. Department of Transportation regulations.

7:28-5.2 Limitations on controlled areas

No area within controlled areas shall be used for residential quarters although a room or rooms in residential buildings may be set apart as a controlled area.

7:28-5.3 Precautionary procedures

(a) Any person having possession, custody or control of any ionizing radiation-producing machine and/or radioactive material shall comply with the following precautionary procedures:

1. Area surveys shall be performed in controlled areas and in adjacent areas to insure that exposure levels to individuals conform to N.J.A.C. 7:28-6. The surveys shall be performed in accordance with N.J.A.C. 7:28-7 pertaining to Radiation survey and personnel monitoring.

2. Wipe tests shall be performed in areas where unsealed sources are routinely used to insure compliance with the requirements for radioactive contamination control in N.J.A.C. 7:28-9. The wipe tests shall be performed in accordance with N.J.A.C. 7:28-7.

3. Personnel surveys shall be performed and documented to insure compliance with N.J.A.C. 7:28-9.

4. All individuals entering a controlled area shall wear personnel monitoring equipment pursuant to the requirements for the use of personnel monitoring equipment in N.J.A.C. 7:28-7.

5. Proper and adequate instruction shall be given to all personnel working in controlled areas in the use of necessary safeguards and procedures, and they shall be supplied with such safety devices as may be required.

6. Adequate instructions or an escort shall be provided to all personnel frequenting or visiting controlled areas as shall be necessary to prevent unnecessary exposure.

7. The area shall be posted in accordance with N.J.A.C. 7:28-10.

7:28-5.4 Termination of controlled areas

Before an area where radioactive materials had been stored, utilized or generated can be reclassified as an uncontrolled area, surveys shall be performed and documented to ensure compliance with N.J.A.C. 7:28-6 for radiation levels outside of controlled areas. Wipe tests shall be performed and documented in areas where unsealed sources had been used or generated.

SUBCHAPTER 6. PERMISSIBLE DOSE RATES, RADIATION LEVELS AND CONCENTRATIONS6. PERMISSIBLE DOSE RATES, RADIATION LEVELS AND CONCENTRATIONS

7:28-6.1 Exposure of individuals in controlled areas

(a) Except as provided in subsection (b) of this Section, no individual in a controlled area shall receive in any period of one calendar quarter a dose in excess of the following specified limits:

1. Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads 1 ¼ Rems;
2. Hands and forearms; feet and ankles 18 ¾ Rems;
3. Skin of whole body 7 ½ Rems.

Note: Doses received by human patients from intentional exposure to radiation for the purpose of diagnosis or therapy shall be excluded.

(b) An individual in a controlled area may receive a dose to the whole body greater than that permitted under subsection (a) of this Section, provided:

1. During any calendar quarter the dose to the whole body shall not exceed three rems;

2. The dose to the whole body, when added to the accumulated occupational dose to the whole body, shall not exceed five (N-18) rems where "N" equals the individual's age in years at his last birthday; and

3. The owner has determined the individual's accumulated occupational dose to the whole body on Form BRP-27, or on a clear and legible record containing all the information required in that form; and has otherwise complied with the requirements of subsection (c) of this Section. As used in this subsection "dose to the whole body" includes any dose to the whole body, gonads, active blood-forming organs, head and trunk, or lens of eye; and

4. Doses received by human patients from intentional exposure to radiation for the purpose of diagnosis or therapy shall be excluded, in the computations set forth in paragraphs 1 and 2 of this subsection.

(c) The following requirements must be satisfied by owners who propose, pursuant to subsection (b) of this Section to permit individuals in a controlled area to receive exposure to radiation in excess of the limits specified in subsection (a) of this Section:

1. Before permitting any individual in a controlled area to receive exposure to radiation in excess of the limits specified in subsection (a) of this Section each owner shall:

i. Obtain a certificate on Form BRP-27, or on a clear and legible record containing all the information required in that form, signed by the individual showing each period of time after the individual attained the age of 18 in which the individual received, or may have received, an occupational dose of radiation; and

ii. Calculate on Form BRP-27, in accordance with the instructions, or on a clear and legible record containing all the information required in that form, the previously accumulated occupational dose received by the individual and the additional dose allowed for that individual under subsection (b) of this Section.

2. In the preparation of Form BRP-27, or on a clear and legible record containing all information required in that form, the owner shall make a reasonable effort to obtain reports of the individual's previously accumulated occupational dose. In any case where an owner is unable to obtain reports of the individual's occupational dose for a previous complete calendar quarter, it shall be assumed that the individual has received the occupational dose

specified in whichever of the following columns apply:

Parts of body	Assumed exposure in rems for calendar quarters prior to Jan. 1, 1961	Assumed exposure in rems for calendar quarters beginning on or after Jan. 1, 1961
Whole body, gonads, active blood-forming organs, head and trunk, lens of eye	3 ¾	1 ¼

3. If calculation of the individual's accumulated occupational dose for all periods prior to Janauary 1, 1961, yields a result higher than the applicable accumulated dose value for the individual as of that date, as specified in subsection (b) of this Section, the excess may be disregarded. The owner shall retain and preserve records used in preparing Form BRP-27, or its equivalent, as specified in subsection (b)3 of this Section.

(d) For individuals within a controlled area, the radiation dose to tissues of the body from radioactive materials within the body shall be controlled by limiting the average rates at which such materials are taken into the body. Where the intake results from the occurrence of radioactive materials in the air, the concentration of the radioisotopes in the air, averaged over any seven consecutive days, shall not be permitted to exceed the concentrations listed in Section 6.5(a) (Average concentrations) of this Chapter, Column B, or prorated values if more than one isotope is present. The limits given in Section 6.5(a) of this Chapter, Column B, are based upon exposure to the concentrations specified for 40 hours in any period of seven consecutive days. In any such period where the number of hours of exposure is less than 40, the limits specified in the table may be increased proportionately. In any such period, where the number of hours of exposure is greater than 40, the limits specified in the table shall be decreased proportionately.

(e) Except as authorized by the Department in writing, no allowance shall be made in subsection (d) of this Section or the use of protective clothing or equipment, or particle size.

1. The Department may authorize an owner to expose an individual in a controlled area to airborne concentrations in excess of the limits specified in Section 6.5(a) of this Chapter, Column B, upon receipt of an application demonstrating that the concentration is composed in whole or in part of particles of such size that such particles are not respirable and that the individual will not inhale concentrations in excess of the limits established in Section 6.5(a) of this Chapter, Column B. Each application under this paragraph shall include an analysis of particle size in the concentrations and a description of the methods used in determining the particle size.

2. The Department may authorize an owner to expose an individual in a controlled area to airborne concentrations in excess of the limits specified in Section 6.5(a) of this Chapter, Column B, upon receipt of an application demonstrating that the individual will wear appropriate protective equipment and that the individual will not inhale, ingest, or absorb quantities of radioactive material in excess of those which might otherwise be permitted under this Chapter for individuals in controlled areas during a 40-hour week. Each application under this paragraph shall contain the following information:

i. A description of the protective equipment to be employed, including the efficiency of the equipment for the material involved;

ii. Procedures for the fitting, maintenance, and cleaning of the protective equipment;

iii. Procedures governing the use of the protective equipment, including supervisory procedures and length of time the equipment will be used by the individuals in each workweek. The proposed periods for use of the equipment by an individual shall not be of such duration as would discourage observance by the individual of the proposed procedures; and

iv. The average concentrations present in the areas occupied by the individuals.

(f) The dose received by any individual under 18 years of age shall not exceed ten per cent of the limits established in subsection (a) of this Section nor shall such an individual be exposed to concentrations of radioactive material greater than those listed in Section 6.5(a) of this Chapter, Column D. For purposes of this subsection, concentrations may be averaged over periods not greater than one week.

7:28-6.2 Radiation levels outside controlled areas

(a) The radiation level at any point outside the confines of the controlled area shall be limited to a value such that there is no reasonable possibility that any individual outside the controlled area will receive a radiation dose to the whole body, head and trunk, active blood-forming organs, gonads, or lens of the eyes, in excess of 0.5 rem in any one year.

(b) The radiation level at any point outside the confines of a controlled area shall not exceed:

1. A radiation level which, if an individual were continuously present in the area, could result in his receiving a dose in excess of two millirems in any one hour; or

2. A radiation level which, if an individual were continuously present in the area, could result in his receiving a dose in excess of 100 millirems in any seven consecutive days.

(c) Any person may apply to the Department for proposed limits upon levels of radiation outside of controlled areas in excess of those specified in subsection (b) of this Section resulting from the applicant's possession or use of sources of radiation. Such applications shall include information as to anticipated average radiation levels and anticipated occupancy times for each area involved. The Department will approve the proposed limits if the applicant demonstrates to the satisfaction of the Department that the proposed limits are not likely to cause any individual to receive a dose to the whole body in any period of one calendar year in excess of 0.5 rem.

(d) The limitations of this Section shall not be applicable to outgoing or incoming shipments of radioactive materials while being transported in conformance with the regulations of Subchapter 14 (Therapeutic Installations).

7:28-6.3 Concentrations in effluents from controlled areas

Concentrations of radioactive materials in effluents from controlled areas shall meet the requirements of Sections 11.2 (Disposal by release into sanitary sewerage systems) and 11.3 (Disposal by discharges into the air, ground waters or surface waters) of this Chapter.

7:28-6.4 Exposures in the event of radiation incidents or emergencies

In the event of a radiation incident in which an employee or emergency worker receives more than

the limits specified in Section 6.1(a) (Exposure of individuals in controlled areas) of this Chapter or in the event of emergency conditions in which immediate action required to minimize danger to life results in an employee or emergency worker receiving doses beyond the limits specified in Section 6.1(a) (Exposure of individuals in controlled areas) of this Chapter. Each employer shall take measures to limit additional exposures of his employees to an extent and for a period, which shall be subject to approval by the Department. All such doses shall be reported as required by Subchapter 13 (Reports of Thefts and Radiation Incidents) of this Chapter and shall be included in the records required by Subchapter 8 (Records) of this Chapter.

7:28-6.5 Average concentrations

(a) Maximum permissible average concentrations of radioactive materials in air and water shall be as follows:

****TABLE OF MAXIMUM PERMISSIBLE****
*****CONCENTRATIONS OMITTED*****

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(b) In any case where there is a mixture in air or water of more than one radionuclide, the limiting values for purposes of this Section shall be determined as follows:

1. If the identity and concentration of each radionuclide in the mixture are known, the limiting values shall be derived as follows:

   i. Determine, for each radionuclide in the mixture, the ratio between the quantity present in the mixture and the limit otherwise established in this Section for the specific radionuclide when not in a mixture.

   ii. The sum of such ratios for all the radionuclides in the mixture may not exceed "1" ("unity").

   iii. For example, if radionuclides A, B, and C are present in concentrations, Ca, Cb, and Cc, and if applicable MPCs and MPCa and MPCb and MPCc respectively, then the concentrations shall be limited so that the following relationship exists:

*****FORMULA OMITTED*****

2. If either the identity or the concentration of any radionuclide in the mixture is not known, the limiting values for purposes of this section are:

   i. For purposes of Column A--3x10-7
   ii. For purposes of Column B--1x10-12
   iii. For purposes of Column C--1x10-8
   iv. For purposes of Column D--4x10-14

3. If any of the conditions specified in this paragraph are met, the corresponding values specified in this paragraph may be used in lieu of those specified in paragraph 2 of this subsection.

   i. If the identity of each radionuclide in the mixture is known but the concentration of one or more of the radionuclides in the mixture is not known, the concentration limit for the mixture is the limit specified in subsection (a) of this Section for the radionuclide in the mixture having the lowest concentration limit;

   ii. If the identity of each radionuclide in the mixture is not known, but it is known that certain radionuclides specified in subsection (a) of this Section are not present in the

mixture, the concentration limit for the mixture is the lowest concentration limit specified in subsection (a) of this Section of any radionuclide which is not known to be absent from the mixture; or

iii. *****TABLE OMITTED*****
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4. If the mixture of radionuclides consists of uranium and its daughter products in ore dust prior to chemical processing of the uranium ore, the values specified in this paragraph may be used in lieu of those determined in accordance with paragraph 1 of this subsection, or those specified in paragraphs 2 and 3 of this subsection.

   i. For purposes of subsection (a) of this Section, Column B, 1x10-10 uc/ml gross alpha activity; or 2.5x10-11 uc/ml natural uranium; or 75 micrograms per cubic meter of air natural uranium.

   ii. For purposes of subsection (a) of this Section, Column C, 3x10-13 uc/ml gross alpha activity; or 8x10-13 uc/ml natural uranium; or 3 micrograms per cubic meter of air natural uranium.

5. For purposes of this subsection, a radionuclide may be considered as not present in a mixture if:

   i. The ratio of the concentration of that radionuclide in the mixture (Ca) to the concentration limit for the radionuclide specified in Columns C and D of subsection (a) of this Section, (MPCa) does not exceed 1/10, that is

      *****FORMULA OMITTED*****

   ii. The sum of such ratios for all the radionuclides considered as not present in the mixture does not exceed ¼; that is

      *****FORMULA OMITTED*****

SUBCHAPTER 7. RADIATION SURVEYS AND PERSONNEL MONITORING7. RADIATION SURVEYS AND PERSONNEL MONITORING

7:28-7.1 Surveys inside controlled areas

(a) Controlled areas shall be surveyed by, or under the direction of, a qualified individual to determine if the installation is maintained and operations are conducted in compliance with this Chapter.

(b) Radiation levels shall be determined with the use of suitable instruments and methods.

(c) Surveys shall be made of the air for radioactive content when the average concentrations may exceed +14 the amount specified in Section 6.5(a) (Average concentrations) of this Chapter, Column B, or prorated values when more than one isotope is present.

(d) Installations when unsealed radioactive materials are stored or used shall be periodically surveyed for contamination of surfaces. These surveys shall be conducted in a manner to insure that the levels of surface contamination are below those which could lead to exposures amounting to ten per cent of the limits specified in Section 6.1(a), (d) (Exposure of individuals in controlled areas) of this Chapter.

(e) The record of a survey shall contain, but shall not be limited to the radiation levels, the time the radiation is produced, the workweek and the fraction of the workweek that any individual may be exposed to the radiation and when required, the radioactive air concentrations and surface contaminations.

(f) Subsequent surveys shall be conducted at such times and as frequently as may be necessary to assure that the controlled areas and operations remain in compliance with this Chapter.

7:28-7.2 Surveys outside controlled areas

Surveys shall be made outside controlled areas at sufficient intervals and locations as may be necessary to insure compliance with Sections 6.2 (Radiation levels outside controlled areas) and 6.3 (Concentrations in effluents from controlled areas) of this Chapter.

7:28-7.3 Statement in lieu of actual survey

A written statement signed by a qualified individual and including his calculations and analysis of the dose rates in the vicinity of a radiation source may be acceptable in place of the survey required in Section 7.1 (Surveys inside controlled areas) of this Chapter, except when radioactive-air contamination or surface contamination is involved.

7:28-7.4 Use of personnel-monitoring equipment

(a) Each owner shall supply appropriate personnel-monitoring equipment to and shall require that it be used by:

1. Each individual who enters a controlled area under such circumstances that he receives, or is likely to receive, a dose in excess of 25 millirems in any period of seven consecutive days;

2. Each individual under 18 years of age who enters a controlled area under such circumstances that he receives or is likely to receive a dose in excess of ten millirems in any period of seven consecutive days;

3. Each individual who enters a high radiation area; and

4. At least one visitor in a group of visitors entering a controlled area.

(b) All individuals required to wear personnel-monitoring equipment shall be instructed in its proper use and purpose. Records shall be kept in accordance with Section 8.1 (Personnel-monitoring records) of this Chapter.

(c) When an individual working on the premises of an owner, but not employed by him is wearing personnel-monitoring equipment provided by his employer, the owner of the radiation source shall not be required to provide additional personnel-monitoring equipment.

7:28-7.5 Requirements for bio-assays

Where necessary or desirable in order to aid in determining the extent of an individual's exposure to concentrations of radioactive material, the Department may incorporate license provisions or issue an order requiring the owner to have appropriate bio-assays made and to furnish the Department with copies of such bio-assays.

SUBCHAPTER 8. RECORDS8. RECORDS

7:28-8.1 Personnel-monitoring records

(a) Clear and legible records shall be maintained by the owner for calendar quarters on Form RH-26,

or on a clear and legible form containing all the information required on RH-26. These records shall show the radiation exposures of all individuals who are required to wear personnel-monitoring equipment according to Section 7.4 (Use of personnel-monitoring equipment) of this Chapter and any required bio-assays according to Section 7.5 (Requirements for bio-assays) of this Chapter.

(b) Each employee, at his request, shall be supplied by the owner with an annual statement of his radiation exposure record and any bio-assays.

(c) At the request of an individual formerly employed by the owner, each owner shall furnish such individual a report of his exposure to radiation, including bio-assays, as shown in records maintained by the owner pursuant to subsection (a) of this Section. Such report shall be furnished within 30 days from the time the request is made or within 60 days from termination of employment, whichever is later. The report shall cover each calendar quarter of the individual's employment involving exposure to radiation.

(d) When an individual working on the premises of an owner, but not employed by him, is required by the owner to wear personnel-monitoring equipment, the owner of the radiation source shall furnish such individual's employer within 90 days a statement of the individual's radiation record and this shall be incorporated in the individual's exposure record.

(e) Each report or statement required by subsections (b) through (d) of this Section shall contain the following statement: "This report is furnished to you under the provisions of Subchapter 8 of the New Jersey Radiation Protection Code. You should preserve this report for future reference."

(f) The exposure records on each employee shall be preserved during the course of his employment and for at least ten years after termination of employment. Exposure records of other persons shall be preserved for at least ten years.

(g) These records or true copy of same shall be made available to the Department on request.

7:28-8.2 Records of surveys

(a) Records shall be maintained showing the results of such surveys as are required pursuant to Subchapter 7 (Radiation Surveys and Personnel Monitoring) of this Chapter.

(b) The records of each survey shall be retained for at least ten years.

(c) These records or true copy of same shall be made available to the Department on request.

(d) The owner of any installation covered in Subchapters 14 through 16 of this Chapter shall submit to the Department within 30 days of receipt a copy of each report of radiation surveys made in compliance with Subchapter 7 (Radiation Surveys and Personnel Monitoring) of this Chapter.

7:28-8.3 Records of radioactive materials

(a) An accurate accounting for all radioactive materials shall be maintained for a radiation installation. Such records shall show radioactive materials received, produced, and disposed, the amounts and form of the radioactive material received or produced and the amount on hand.

(b) Such records shall be retained for at least two years after the final disposition of any radioactive material.

(c) These records or true copy of same shall be made available to the Department on request.

7:28-8.4 Records of sealed source testing

Records of the results of sealed source testing shall be kept at least two years.

7:28-8.5 Records from discontinued installations

The discontinuance of a radiation installation does not relieve the owner from the responsibility of retaining the records required by this Subchapter. Such owner may, however, request the Department to accept the records. The acceptance of such records by the Department relieves the owner of subsequent responsibility only in respect to their preservation as required by this Chapter.

SUBCHAPTER 9. RADIOACTIVE CONTAMINATION CONTROL9. RADIOACTIVE CONTAMINATION CONTROL

7:28-9.1 General precautions

All work with radioactive materials shall be carried out under such conditions as to minimize the radioactive contamination of the area and of the person(s) working therein.

7:28-9.2 Personnel and material contamination

(a) When the nature of the work is such that an individual or his clothing may become contaminated, the individual and his clothing shall be suitably monitored.

(b) Any contamination which might lead to exposures greater than ten per cent of the limits specified in Section 6.1(a) or (d) (Exposure of individuals in controlled areas) of this Chapter shall be removed from the contaminated individual before that individual is permitted to leave the area.

(c) No clothing, equipment, or other material having contamination which might lead to exposures greater than those specified in subsection (b) of this Section shall be permitted to leave the area except as radioactive material.

7:28-9.3 Decontamination of premises

Radioactively contaminated premises shall be decontaminated so that individuals using these premises shall not receive exposures greater than those listed in Section 9.2 (b) (Personnel and material contamination) of this Chapter.

7:28-9.4 Sealed source testing

(a) Unless otherwise specified in a Federal agency license, or a State license, sealed sources except tritium and krypton, containing more than ten times the exempt quantities of Section 3.6 (Table of exempt quantities) of this Chapter, shall be leak tested than ten times the generally licensed quantities of Section 4.19 (Quantities generally licensed) of this Chapter, Column B, or more at intervals of not longer than six months.
(b) Records of all sealed source testing shall be kept in accordance with Section 8.4 (Records of sealed source testing) of this Chapter.

SUBCHAPTER 10. LABELING, POSTING, AND CONTROLS10. LABELING, POSTING, AND CONTROLS

7:28-10.1 General requirement

(a) All signs and labels required by this Subchapter shall use the conventional radiation caution symbol shaped and colored as follows:

1. Cross-hatched area is to be magenta or purple;

2. Background is to be yellow.

(b) In addition to the language prescribed in the various sections of this Subchapter, any supplementary information which might be appropriate in aiding individuals to minimize exposure to radiation or to radioactive materials may be provided on or near such required signs or labels.

7:28-10.2 Radiation areas

(a) Each radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

1. CAUTION—RADIATION AREA; or
2. DANGER—RADIATION AREA

7:28-10.3 High radiation areas

(a) Each high radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

1. CAUTION—HIGH RADIATION AREA; or
2. DANGER—HIGH RADIATION AREA

(b) Each high radiation area shall be under direct, constant surveillance to protect against unauthorized or accidental entry unless:

1. It is equipped with a control device which shall cause the level of radiation to be reduced below that at which an individual might receive a dose of 100 millirems in one hour upon entry into the area;

2. It is equipped with a control device which shall energize a conspicuous visible or audible alarm signal in such a manner that the individual entering and the owner or the supervisor of the activity are made aware of the entry; or

3. It is locked to protect against unauthorized or accidental entry and the owner or the supervisor of the activity maintains direct personal control over access to the key.

7:28-10.4 Airborne radioactivity areas

(a) Each airborne radioactivity area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

1. CAUTION—AIRBORNE RADIOACTIVITY AREA; or
2. DANGER—AIRBORNE RADIOACTIVITY AREA

7:28-10.5 Areas containing radioactive materials

(a) Each area or room in which radioactive material, other than natural uranium or thorium is used or stored in an amount greater than ten times that listed in Section 10.9 (Labeling, posting and disposal quantities of radioactive material) of this Chapter shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

1. CAUTION—RADIOACTIVE MATERIAL(S); or
2. DANGER—RADIOACTIVE MATERIAL(S)

(b) Each area or room in which natural uranium or thorium is used or stored in an amount exceeding 100 times the quantity listed in Section 10.9 (Labeling, posting and disposal quantities of radioactive material) of this Chapter shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

1. CAUTION—RADIOACTIVE MATERIAL(S); or
2. DANGER—RADIOACTIVE MATERIAL(S)

7:28-10.6 Labeling of equipment and containers

(a) Any equipment or container in which radioactive material, other than natural uranium or thorium, is transported, stored, or used, in an amount greater than that specifically listed in Section 10.9 (Labeling, posting and disposal quantities of radioactive material) of this Chapter shall bear a durable, clearly visible label bearing the radiation caution symbol and the words:

1. CAUTION—RADIOACTIVE MATERIAL; or
2. DANGER—RADIOACTIVE MATERIAL

(b) Each container in which natural uranium or thorium is transported, stored, or used in a quantity greater than 10 times the quantity listed in Section 10.9 (Labeling, posting and disposal quantities of radioactive material) of this Chapter shall bear a durable, clearly visible label bearing the radiation caution symbol and the words:

1. CAUTION—RADIOACTIVE MATERIAL; or
2. DANGER—RADIOACTIVE MATERIAL

(c) Where containers are used for storage, the labels required in this Section shall state also the quantities and kinds of radioactive materials in the containers and the date of measurement of the quantities.

(d) All radiation-producing machines capable, when operated, of producing a radiation area shall be labeled in a manner which cautions individuals of this fact.

7:28-10.7 Removal of signs and labels

All radiation caution signs and labels which may have been posted at a time when they were required shall be removed when the condition which originally required the posting no longer exists.

7:28-10.8 Exceptions from posting and labeling requirements

(a) Radiation areas and high radiation areas which result from the operation of therapeutic x-ray machines operated at potentials of 60 kv and below or from the operation of diagnostic x-ray machines shall be exempt from the posting requirements of Sections 10.2, 10.3 and 10.6(d) of this Chapter provided that the operator of the equipment has taken precautions to insure that no individual other than the patient shall be in the radiation area.

(b) Rooms or other areas in hospitals are not required to be posted with radiation caution signs because of the presence of patients containing radioactive material provided that there are personnel in attendance who shall take the precautions necessary to prevent the exposure of any individual other than the patient to radiation or radioactive material in excess of the limits established in this Chapter.

(c) A room or area is not required to be posted with a radiation caution sign because of the presence of a sealed source provided the radiation level 12 inches from the surface of the source container or source housing does not exceed five millirems per hour.

(d) Radiation caution signs are not required to be posted at areas or rooms containing radioactive materials for periods of less than eight hours provided that:

1. The materials are constantly attended during such periods by an individual who shall take the precautions necessary to prevent the exposure of any other individual to radiation or radioactive materials in excess of the limits established in these regulations; and

2. Such area or room is subject to the user's control.

(e) Laboratory containers such as beakers, flasks and test tubes need not be labeled if they are being used transiently in laboratory procedures when the user is present.

(f) A container in which radioactive material is transported, stored, or used need not be labeled, if the concentration of the material in the container does not exceed that specified in Section 6.5(a) (Average concentrations) of this Chapter, Column A.

(g) Radioactive materials packaged and labeled in accordance with regulations of the appropriate Federal agency shall be exempt from the labeling and posting requirements of this Section during shipment, provided that the inside containers are labeled in accordance with the provisions of Section 10.6 (Labeling of equipment and containers) of this Chapter.

7:28-10.9 Labeling, posting and disposal quantities of radioactive materials

(a) Microcuries table is as follows:

*****TABLE OMITTED*****

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(b) For purposes of Section 10.5 (Areas containing radioactive material) and 10.6 (Labeling of equipment and containers), where there is involved a combination of isotopes in known amounts, the limit for the combination shall be derived by determining for each isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of such ratios for all the isotopes in the combination may not exceed "1" ("unity").

SUBCHAPTER 11. DISPOSAL OF RADIOACTIVE MATERIALS11. DISPOSAL OF RADIOACTIVE MATERIALS

7:28-11.1 General requirements

The disposal of radioactive materials is permitted only to the extent and under the conditions specified in Sections 11.2 through 11.7 of this Chapter.

7:28-11.2 Disposal by release into sanitary sewerage systems

(a) An owner may discharge radioactive material into a sanitary sewerage system providing:

1. It is readily soluble or dispersible in water;

2. The quantity of any radioactive material released into the system by the owner in any one day does not exceed the larger of subparagraphs (i) or (ii) of this paragraph:

i. The quantity which, if diluted by the average daily quantity of sewage released into the sewer by the owner, will result in an average concentration not greater than the limits

specified in Section 6.5(a) (Average concentrations) of this Chapter, Column A, or prorated values if more than one isotope is released; or

ii. Ten times the quantity of such material specified in Section 10.9 (Labeling, posting and disposal quantities of radioactive materials) of this Chapter; and

3. The quantity of any radioactive material released in any one month, if diluted by the average monthly quantity of sewage released by the owner, will not result in an average concentration exceeding the limits specified in Section 6.5 (a) (Average concentrations) of this Chapter, Column A, or prorated values if more than one isotope is released; and

4. The gross quantity of radioactive material released into the sewerage system by the owner does not exceed one curie per year.

(b) Radioactive wastes excreted by humans shall be exempt from the limitations of subsection (a) of this Section.

7:28-11.3 Disposal by discharges into the air, ground waters or surface waters

(a) An owner may dispose of radioactive material into the air outside a controlled area provided the concentration at the point where the material leaves the controlled area is not in excess of the concentration specified in Section 6.5 (a) (Average concentrations) of this Chapter, Column D, or prorated values if more than one isotope is discharged. Where the material is discharged through a stack, tube pipe, or similar conduit, the determination may be made with respect to the point where the material leaves such conduit. For purposes of this subsection, concentrations may be averaged over periods not greater than one year.

(b) No owner shall dispose of radioactive material into surface waters or into ground waters without specific, prior permission in writing from the Department.

7:28-11.4 Disposal by burial in the soil

(a) No owner shall dispose of radioactive material by burial in the soil without prior approval in writing from the Department.

(b) Sites that have been used for burial of radioactive materials shall not be converted to other uses except with the written permission of the Department.

(c) The owner of any burial ground shall notify the Department in writing not less than 30 days in advance of any transfer of title to the property involved.

7:28-11.5 Disposal by transfer to a radioisotope disposal service

(a) An owner may dispose of radioactive materials by transfer to a radioisotope disposal service providing this service has been approved by the Department to receive such materials.

(b) An owner may dispose of radioactive materials by transfer to a person who is authorized to receive such material under a license issued by the Department, a Federal agency, or any agreement state.

7:28-11.6 Disposal by incineration

No owner shall incinerate radioactive materials for the purpose of disposal or preparation for disposal except as specifically approved by the Department in writing.

7:28-11.7 Disposal by a specially approved method

(a) Any person may apply to the Department for approval of proposed procedure to dispose of radioactive material in a manner not otherwise authorized in this Subchapter.

(b) Each application shall include a description of the radioactive material, including the quantities and kinds of radioactive material and the levels of radioactivity involved, and the proposed manner and conditions of disposal.

(c) The application, where appropriate, shall also include an analysis and evaluation of pertinent information as to the nature of the environment, including topographical, geological, meteorological, and hydrological characteristics; usage of ground and surface waters in the general area; the nature and location of other potentially affected facilities; and procedures to be observed to minimize the risk of unexpected or hazardous exposures.

7:28-11.8 Unauthorized removal

Sources of radiation shall be secured against unauthorized removal from the place of storage.

SUBCHAPTER 12. TRANSPORTATION12. TRANSPORTATION

7:28-12.1 Purpose and scope

(a) This subchapter establishes requirements for transportation of radioactive material and for approval by the Department of shipping procedures for certain quantities of radioactive materials as defined in N.J.A.C. 7:28-12.3.

(b) The provisions of this subchapter shall apply to the transportation of certain quantities of radioactive materials into, through or within the State of New Jersey and to any storage of such materials during or pending such transportation notwithstanding the applicability of other provisions of this chapter or compliance with other applicable law or regulations.

7:28-12.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings unless the context clearly indicates otherwise.

"Certificate of handling" means a written document issued by the Department approving the use of certain specified New Jersey routes for the transport of specified quantities of radioactive materials.

"Certificate of handling for intransit storage" means a written document issued by the Department approving the use of a specifically designated location for the temporary storage of specified quantities of radioactive materials.

"Certification number" means the number associated with the written document issued by the Department.

"Certified shipment" means a shipment which meets the certification requirements as set forth in this subchapter.

"Intransit storage" means the strong, holding, or otherwise detaining of radioactive material during shipment at a location other than its ultimate delivery point or point where material is to be used, processed, disposed of or otherwise utilized.

"Irradiated reactor fuel" means materials used as a source of fuel in a nuclear reactor and which have been subjected to neutron bombardment.

"Radiopharmaceutical" means a radionuclide or radioactive compound designed and prepared for organ or body system administration.

7:28-12.3 General requirements

(a) No person shall cause, suffer, allow or permit the transportation, intransit storage or detention pending transportation of any of the following materials without first having obtained a certificate of handling or a certification number in advance of such certificate from the Department:

1. Plutonium isotopes in any quantity and form exceeding two grams or 20 curies, whichever is less;

2. Uranium enriched in the isotope U-235 exceeding 25 atomic percent of the total uranium content in quantities where the U-235 content exceeds one kilogram;

3. Any quantity of radioactive material which, when combined with any other quantity of such material, exceeds 20 curies including, but not limited to, any of the actinides, spent reactor fuel elements or mixed fission products associated with such spent fuel elements.

(b) In the case of intrastate shipments, no person shall cause, suffer, allow or permit the transportation or intransit storage of any amount of radioactive material outside the confines of the location authorized for its use unless there is compliance with all relevant rules and regulations, as amended, of the United States Department of Transportation, United States Nuclear Regulatory Commission, and the United States Postal Service to the same extent as if the transportation were subject to the rules and regulations of that agency directly.

7:28-12.4 Application for certificate of handling for the transportation of radioactive material

(a) No person shall cause, suffer, allow or permit the transportation of radioactive material in quantities specified in N.J.A.C. 7:28-12.3(a) without having first obtained a certificate of handling or a certification number in advance of such certificate from the Department.

(b) All shipments of radioactive material shall be accompanied by either a certificate of handling or a certification number issued by the Department.

1. In those cases where a certificate of handling is issued by the Department, the certificate of handling shall be included with the shipping documents accompanying the certified shipment;

2. In those cases where a certification number is issued by the Department, the certification number and a 24-hour emergency telephone number will be supplied by the Department for notifying the State Police in the event of a public safety accident. Both the certification number and 24-hour emergency telephone number shall appear on all shipping documents accompanying the certified shipment;

3. All documents accompanying a certified shipment shall be available for inspection by authorized enforcement personnel.

(c) All applications for a certificate of handling or certification number shall be made to the Department not less than seven business days prior to shipment and shall include the following information:

1. Name of shipper;
2. Name of carrier and name of driver;
3. Type and quantity of radioactive material;
4. Date and time of shipment;
5. Starting point, scheduled route and destination;
6. Year, make, color, state of registration and plate number of vehicle, if applicable;

7. Names and phone numbers of individuals with knowledge as to the type and quantity of material, who will be available on a 24-hour basis to assist in radiological assessment in the event of a public safety accident;
8. An affidavit of insurance which complies with the requirements of subsection (j) of this section;
9. Any additional information required by the Department.

(d) The Department may require changes in dates, routes or time of transporting such material, if necessary, to maximize protection to public health and safety.

(e) The Department, upon receipt of the information specified in subsection (c) of this section and after consultation with the Superintendent of State Police, may approve an application for a certificate of handling or a certification number, if it determines that the shipment of such material shall be accomplished in a manner which does not jeopardize the public health and safety.

(f) Where the applicant supplies a shipping schedule for a number of shipments along with the information specified in subsection (c) of this section for each shipment, the Department, after consultation with the Superintendent of State Police, may issue certificates of handling or certification numbers for the specified shipment for a period not exceeding one year in advance of any shipment.

(g) The Department may issue yearly certificates of handling or yearly certification numbers for the routine shipment of radioactive materials.

(h) In the case of certain shipments, the Department may require an escort and special handling and may prohibit any shipment until the applicant has satisfactorily demonstrated that he has arranged, at his own expense, such escort or other special handling.

1. Where an escort or other special handling is required, the applicant shall submit the plans or specifications for review and approval by the Department and by the Superintendent of State Police.

2. The Superintendent of State Police reserves the right to disapprove such specifications and to require such modifications as deemed appropriate or in certain extraordinary cases to direct that any shipment be prohibited until a State Police escort or other action can be arranged. Any condition stipulated by the State Police will be imposed by the Department as a condition of the certificate of handling.

(i) All certified shipments which do not require placarding on the outside of the shipping vehicle shall have a placard conspicuously posted in the cab to be readily visible from outside the cab of the vehicle bearing the conventional radiation symbol and the words:

"CAUTION: THIS VEHICLE CONTAINS RADIOACTIVE MATERIAL"

(j) The applicant shall have adequate insurance coverage in order to indemnify all parties against injury, loss, or damage resulting from accidents.

(k) The Department may amend or revoke any certificate of handling issued pursuant to this subchapter whenever it has cause to believe that the information upon which the certificate is issued is in any way inaccurate, incomplete or otherwise invalid.

7:28-12.5 Application for a certificate of handling for the transportation of irradiated reactor fuel (spent

fuel)

(a) No person shall cause, suffer, allow or permit the transportation of irradiated reactor fuel without first having obtained certificate of han-dling from the Department.

(b) All shipments of irradiated reactor fuel shall be accompanied by a certificate of handling issued by the Department.

(c) The certificate of handling shall include the shipping documents accompanying the certified shipment. All such documents shall be available for inspection by authorized enforcement personnel.

(d) In order to obtain a certificate of handling for the shipment of irradiated reactor fuel, the applicant shall satisfy the following requirements in addition to any other regulations applicable to irradiated reactor fuel shipments.

(e) All applications for a certificate of handling shall be made to the Department in writing not less than 30 days prior to the planned shipment date and shall include the following information:

1. Name of shipper;
2. Name of carrier;
3. Type and quantity of radioactive material, including the number of fuel assemblies and activity in Curies;
4. Date of shipment;
5. Starting point, schedule route, and destination including mileage and estimated elapsed time for each distinct segment of the route within New Jersey. The scheduled shipment shall comply with the requirements of subsections (i), (j), (k), and (m) of this section;
6. Type of transport vehicle, cask identification, and loaded weight of the transport vehicle;
7. A written safeguard plan which shall include procedures for the physical protection of the irradiated reactor fuel shipment which complies with, but is not limited to, the requirements of subsections (h) and (l) of this section;
8. Any unusual characteristics of the shipment that would require special preparations or countermeasures in the event of a transportation emergency;
9. Names and phone numbers of available personnel responsible for emergency control and cleanup;
10. The names and phone numbers of individuals with knowledge of the type and quantity of material who will be available on a 24-hour basis to assist in radiological assessment in the event of a public safety accident;
11. An affidavit of insurance which complies with the requirements of subsection (g) of this section; and
12. Any additional information required by the Department.

(f) Upon approval, all applicants shall update and verify information given to the Department on the original application, and shall provide the Department with the following additional information in writing not less than seven days prior to the approved shipment date:

1. Time of shipment, including starting time, and if applicable, estimated time of entry into the departure from the State of New Jersey;
2. Names of personnel accompanying shipment;
3. Year, make, color, state of registration, and plate number of vehicles escorting the shipment, if applicable; and
4. Means by which the Department can contact the transport and escort vehicles while enroute in New Jersey.

(g) The applicant shall have adequate insurance coverage in order to indemnify all parties against injury, loss, or damage resulting from accident.

(h) The applicant shall provide a statement setting forth arrangements made with law enforcement agencies along the route of the shipment for their response to an emergency or call for assistance.

(i) The proposed route shall utilize railways, roadways, or other transport modalities deemed safe by the Department and State Police. For road shipments, the applicant shall use major highways in all routing except where the Department judges such routing would place a greater threat to the public health and safety than alternate routing, or where secondary roadways must be used for a minimum distance for egress from the point of origin or ingress to the final destination.

(j) In addition to compliance with all applicable standards, the applicant shall not transport in any county in New Jersey which has a population density exceeding 1,000 persons per square mile as measured in the most recent decennial census. The Department may waive this requirement only when it is shown to the satisfaction of the Department that routing excluding densely populated areas would place a greater threat to the public health and safety than routing traversing these areas.

(k) If, in accordance with subsection (j) of this section, movement through a densely populated area is unavoidable, the following additional measures shall be taken:

1. Transit of the irradiated reactor fuel shall be nonstop. Provisions shall be made in advance so that refueling will be necessary in densely populated areas.

2. Primary roads shall be used for road shipments.

3. Protection by an armed escort force consisting of local police or trained armed private guards shall be provided by the shipper. At least two armed guards in a separate vehicle shall accompany the transport vehicle for road shipments.

4. No movement of irradiated reactor fuel shall occur through densely populated areas between 7:00 A.M. and 9:00 A.M. and 4:00 P.M. and 6:00 P.M.

(l) Each shipment of irradiated reactor fuel shall be accompanied by an armed escort; the plans and specifications for which shall be submitted at the time of application for review by the Department and Superintendent of State Police.

(m) The shipment of irradiated reactor fuel shall be scheduled wherever practicable without any intermediate stops within New Jersey except for refueling and obtaining provisions, and at all stops, at least one individual shall maintain constant surveillance of the transport vehicle. Irradiated reactor fuel is specifically excluded from the provisions of N.J.A.C. 7:28-12.7.

(n) The Superintendent of State Police reserves the right to disapprove escort or special handling specifications and to require such modifications as deemed appropriate or, in certain extraordinary cases, to direct that any shipment be prohibited until a State Police escort or other action can be arranged. Any conditions stipulated by the State Police will be imposed by the Department as a condition of the certificate of handling.

(o) The Department may require changes in dates, routes, or time of transporting irradiated reactor fuel if necessary to maximize protection of the public health and safety.

(p) The Department will issue certificates of handling for individual shipments only. Irradiated reactor fuel is specifically excluded from the provisions of N.J.A.C. 7:28-12.4(f) and (g).

(q) The Department, upon review of the information specified in subsection (e) of this section, and after consultation with the Superintendent of State Police, may approve the application for a certificate of handling if it determines that the shipment shall be accomplished in a manner which does not jeopardize the public health and safety.

(r) The Department may amend or revoke any certificate of handling issued pursuant to this section whenever it has cause to believe that the information upon which the certificate is issued is in any way inaccurate, incomplete, or otherwise invalid or has not been verified pursuant to subsection (f) of this section.

7:28-12.6 Application for certificate of handling for the transportation of radiopharmaceuticals or radiographic exposure devices

(a) No person shall transport or cause, suffer, allow or permit the shipment of radiopharmaceuticals or radiochemicals used to produce such radiopharmaceuticals or radiographic exposure devices in quantities of 20 or more curies without first obtaining a certificate of handling from the Department.

(b) The Department, after consultation with the Superintendent of State Police, may issue to the applicant a certificate of handling for a period not exceeding one year subject to fulfillment of the following conditions by the applicant.

1. The applicant shall submit a written application to the Department containing the information required by N.J.A.C. 7:28-12.4(c)1 to 9 except that where such information is unavailable at the time the application is made, the applicant shall submit his best judgment as to such information and report deviations in accordance with paragraph 3 of this subsection.

2. The applicant shall submit a report to the Department which supplies the specific information required by N.J.A.C. 7:28-12.4(c)3, 4, 5 for each shipment. Such reports shall be received by the Department not later than 30 days following each of the following periods or partial period during which the certificate of handling is in force: January 1 to March 31; April 1 to June 30; July 1 to September 30; October 1 to December 31.

3. The applicant shall request approval from the Department whenever a shipment deviates from the general conditions set forth in the applicant's annual certificate of handling.

4. When an applicant consistently or routinely applies to the Department for approval of deviations from the annual certificate of handling, the Department may require the applicant to reapply for new annual certificate of handling.

5. In the case of radiographic exposure devices, a statement shall be submitted that such devices and the radiation sources utilized therein meet all the requirements of N.J.A.C. 7:28-17.1 et seq.

7:28-12.7 Application for certificate of handling for the storage of intransit radioactive material

(a) No person shall cause, suffer, allow or permit any intransit storage of radioactive material unless measures are taken to insure that the material cannot be removed by other than authorized personnel, and to insure compliance with such provisions of N.J.A.C. 7:28-6.1 et seq., 7.1 et seq., and 8.1 et seq. as the Department may have imposed, on a case by case basis, as a condition of certification.

(b) Any person who holds, detains or otherwise stores radioactive material while intransit, where the combined amounts of radioactive materials continually or periodically exceed the quantities specified in N.J.A.C. 7:28-12.3, shall apply for a certificate of handling for intransit storage.

(c) Any person seeking to obtain a certificate of handling for intransit storage shall submit to the Department the following information:

1. The type, maximum quantity, and maximum time period for storage of each radioactive material to be stored;

2. A description of the location and manner of storage;

3. Names, addresses and telephone numbers of the chiefs of local police and fire departments of the jurisdiction in which the storage facility is situated;

4. Names and phone numbers of individuals, with knowledge as to the type and quantities of materials in storage, who will be available on a 24-hour basis to assist in radiological assessment in the event of a public safety accident;

5. An affidavit of insurance which complies with the requirements of subsection (g) of this section;

6. Any additional information required by the Department.

(d) The Department, upon receipt of the information specified in subsection (c) of this section, after consultation with the Superintendent of State Police, may issue to the applicant a certificate of handling for intransit storage upon finding that such material will be stored in a manner which does not jeopardize the public health or safety.

(e) Any person storing radioactive material while such material is in transit shall immediately notify the Department of any additions in type, or increases in quantities or length of time of storage.

(f) The certificate of handling for intransit storage shall be posted prominently in the storage facility.

(g) The applicant shall have adequate insurance coverage in order to indemnify all parties against injury, loss, or damage resulting from accidents.

7:28-12.8 Noncompliance with certification conditions

(a) Any person who deviates from the conditions of any certificate of handling issued by the Department, or who handles radioactive material in nonconformity with the required information submitted in applying for a certificate of handling, shall be considered to be transporting, storing or otherwise handling radioactive material without such certificate.

(b) Any person who knowingly makes any false statement on any application, label shipping document, record, report or other document required to be submitted to the Department or maintained pursuant to these regulations shall, upon conviction, be guilty of a crime of the fourth degree.

7:28-12.9 Fees

The Department may charge fees for any service performed pursuant to this subchapter in accordance with a fee schedule promulgated pursuant to N.J.S.A. 26:2D-1 et seq., if it determines that such is necessary for the efficient implementation of the provisions of this subchapter.

SUBCHAPTER 13. REPORTS OF THEFTS AND RADIATION INCIDENTS13. REPORTS OF THEFTS AND RADIATION INCIDENTS

7:28-13.1 Reports of theft or loss of radioactive materials

The owner from whose possession a theft or loss occurs shall immediately notify the Department by telephone and telegraph of any theft or loss of radioactive material in such quantities and under such circumstances that a substantial radiation hazard and/or contamination hazard may result.

7:28-13.2 Reportable radiation incidents

(a) The owner shall immediately notify the Department by telephone and telegraph of any radiation incident which may have caused or threatens to cause the following:

1. Exposure of the whole body of any individual to 25 rems or more of radiation; exposure of the skin of the whole body of any individual to 150 rems or more of radiation; or exposure of the feet, ankles, hands or forearms of any individual to 375 rems or more of radiation;

2. The release of radioactive material in concentrations which, if averaged over a period of 24 hours, would exceed 5,000 times the limits specified for such materials in Section 6.5(a) (Average concentrations) of this Chapter Columns C and D, or prorated values if more than one isotope is released;

3. A loss of one working week or more of the operation of any facilities affected; or

4. Damage to property in excess of $100,000.

(b) The names of any individuals who have been exposed to radiation levels set forth in subsection (a) of this Section shall not be included in the report.

(c) The owner shall notify the Department within 24 hours by telephone and telegraph of any radiation incident which may have caused or threatens to cause the following:

1. Exposure of the whole body of any individual to five rems or more of radiation; exposure of the skin of the whole body of any individual to 30 rems or more of radiation; or exposure of the feet, ankles, hands or forearms to 75 rems or more of radiation;

2. The release of radioactive material in concentrations which, if averaged over a period of 24 hours, would exceed 500 times the limit specified for such materials in Section 6.5(a) (Average concentrations) of this Chapter Columns C and D, or prorated values if more than one isotope is released;

3. A loss of one day or more of the operation of any facilities affected; or

4. Damage to property in excess of $1,000.

(d) The names of any individuals who have been exposed to radiation levels set forth in subsection (c) of this Section shall not be included in the report.

(e) The owner shall notify the Department in writing within 30 days of the following:

1. Each exposure of an individual to radiation or concentrations of radioactive material in excess of any applicable limit of Subchapter 6 (Permissible Dose Rated, Radiation Levels and Concentrations) of this Chapter, or of a licensee's license;

2. Any incident for which notification is required by subsections (a) and (c) of this Section; or

3. Levels of radiation or concentrations of radioactivity, not involving exposure of any individual in excess of any applicable limit Subchapter 6 (Permissible Dose Rated, Radiation Levels and Concentrations) of this Chapter, outside a controlled area in excess of ten times the limits of Section 6.2 (Radiation levels outside controlled areas) and Subchapter 11 (Disposal of Radioactive Materials) of this Chapter, or of a licensee's license.

(f) The reports set forth in subsection (e) of this Section shall describe the extent of exposure of individuals to radiation or to radioactive materials, the levels of radiation and concentrations of radioactive materials involved, the cause of the exposure, levels, or concentrations and corrective steps taken or planned to assure against a recurrence.

(g) In each case where subsection (e)1 of this Section requires a report to the Department of exposure of an individual, the owner shall:

1. Delete from the report all references to the names and addresses of individuals so exposed. The identity of such individuals shall be privileged and shall be submitted as a separate document of such report; and

2. Concurrently given written notification to the individual of the nature and extent of the exposure. Such notice shall contain the following statement: "This report is furnished to you under the provisions of Subchapter 13 (Reports of Thefts and Radiation Incidents) of the New Jersey Administrative Code. You should preserve this report for future reference."

SUBCHAPTER 14. THERAPEUTIC INSTALLATIONS14. THERAPEUTIC INSTALLATIONS

7:28-14.1 Scope

(a) This subchapter covers therapeutic installations used in the healing arts. These therapeutic installations include x-ray, accelerator and teletherapy installations. No registrant shall operate or permit the operation of therapeutic equipment used in the healing arts unless the equipment and installation meet the applicable requirements of this subchapter.

7:28-14.2 Definitions

The following words and terms, when used in this subchapter shall have the following meanings, unless the context clearly indicates otherwise.

"Applicator" means a structure which determines the extent of the treatment field at a given distance from the virtual source and which may or may not incorporate the beam limiting device.

"Beam interceptor" means a device located on the central axis of the primary beam whose purpose is to substantially attenuate the beam so that the room shielding requirements may be reduced.

"Beam limiting device" means a device which provides a means to restrict the dimensions of the radiation field and which is an integral part of the equipment.

"Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.

"Beam scattering filter" means a filter used to scatter a beam of electrons.

"Central axis of the beam" means a line passing through the virtual source and the center of the plane figure formed by the edge of the final beam limiting device.

"Contact therapy system" means an x-ray system used for therapy not capable of operating above 60 kVp and with a source distance less than or equal to five centimeters.

"Department" means the New Jersey Department of Environmental Protection.

"Dose monitoring system" means a system of devices for the detection, measurement, and display of dose information for the useful beam.

"Dose monitor unit" means a unit response from the dose monitoring system from which the absorbed dose can be calculated.

"Field flattening filter" means a filter used to provide dose uniformity over the area of a useful beam of x-rays at a specified depth.

"Field size" means the projection on a plane perpendicular to the beam axis, of the distal end of the collimator as seen from the front center of the source.

"Full beam detector" means a radiation detector of such size that the total cross section of the maximum-size useful beam is intercepted.

"Gantry" means that part of the system supporting and allowing possible movements of the radiation head.

"Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

"Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

"Isocenter" means a fixed point in space located at the center of the smallest sphere through which the central axis of the beam pass.

"Leakage radiation" means radiation emanating from the diagnostic or therapeutic source assembly except for the useful beam.

"Moving beam therapy" means radiation therapy with relative movement of the useful beam and the patient during irradiation.

"Normal treatment distance" means:

1. For electron irradiation, the nominal source to surface distance along the central axis of the useful beam, specified by the manufacturer for the applicator;

2. For x-ray irradiation, the nominal source to isocenter distance along the central axis of the useful beam; and

3. For non-isocentric equipment, this distance shall be specified by the manufacturer.

"Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

"Primary dose monitoring system" means a system which will monitor the quantity of radiation produced during irradiation and which will termi-nate irradiation when a pre-selected number of dose monitor units have been delivered.

"Qualified radiological physicist" means a person who holds at least a bachelor's degree in one of the physical sciences and who is certified by the American Board of Radiology either in radiological physics, x- and gamma ray physics or therapeutic radiological physics, is eligible for such certification, or has equivalent training and experience.

1. "Equivalent training and experience" means a person has:

i. A bachelor's degree in physical sciences and three years full time experience working under the direction of a physicist certified by the American Board of Radiology;

ii. A doctorate or master's degree in physical science and two years such experience; or

iii. A doctorate or master's degree in radiological or medical physics and two years of full-time, post-doctoral training with clinical experience.

"Registrant" means the person required to register with the Department pursuant to N.J.A.C. 7:28-3.

"Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary system.

"Spot check" means an abbreviated calibration procedure which is performed to assure that a previous calibration continues to be valid.

"Stationary beam therapy" means radiation therapy without relative movement of the useful beam and the patient during irradiation.

"Target" means that part of a radiation-producing device used to intercept a beam of accelerated particles and cause emission of other radiation.

"Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

"Transmission detector" means a radiation detector through which the useful beam or part of the useful beam passes.

"Traceable to national standards" means a dosimetry system calibrated by the National Bureau of Standards (NBS) or calibrated in a beam which has been standardized by a transfer-grade ionization chamber having a NBS calibration.

"Treatment field" means the area of the patient's skin which is to be irradiated.

"Virtual source" means a point from which radiation appears to originate.

"Wedge filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

7:28-14.3 Therapeutic x-ray systems with energies less than one MeV

(a) Equipment requirements for therapeutic x-ray systems with energies less than one MeV are as follows:

1. Leakage radiation shall be measured under conditions which provide maximum leakage radiation, the leakage radiation shall not exceed the value specified at the distance specified for the classification of that x-ray system. Compliance shall be determined by measurements averaged over an area of 100 square centimeters. Measurement shall be performed at installation and whenever the tube is changed. Measurement shall be performed at least once every five years;

i. For Contact Therapy Systems, leakage radiation shall not exceed 100 milliroentgens in one hour at five centimeters from the surface of the tube housing assembly;

ii. For 0-150 kVp Systems which are installed prior to October 1, 1987, leakage radiation shall not exceed one roentgen in one hour at one meter from the target;

iii. For 0-150 kVp Systems which are installed on or after October 1, 1987, leakage

radiation shall not exceed 100 milliroentgens in one hour at one meter from the target;

iv. For 151 to 500 kVp Systems the leakage radiation shall not exceed one roentgen in one hour at one meter from the target;

v. For 501 to 999 kVp Systems the leakage radiation at a distance of one meter from the target shall not exceed 0.1 percent of the useful beam exposure rate at one meter from the target; and

vi. Records of leakage radiation shall be maintained at the facility for at least five years and shall be made available for inspection by the Department.

2. Beam limiting devices for equipment installed on or after October 1, 1987 shall transmit no more than one percent of the useful beam, for the portion of the beam which is to be attenuated by the beam limiting device, when the equipment is operating at maximum kVp and with maximum filtration. Measurements shall be made at a distance of one meter from the beam limiting device and in a plane perpendicular to the central axis of the beam. For equipment installed before October 1, 1987, transmissions shall not exceed five percent of the useful beam;

3. The filter system shall be so designed that:

i. It will minimize the possibility of error in filter selection;

ii. Filters cannot be accidentally displaced from the useful beam at any possible tube orientation;

iii. Each filter is marked as to its material of construction and its thickness or wedge angle for wedge filters;

iv. It shall be possible for the operator to determine the presence or absence of any filter in the useful beam when the operator is at the control panel, either by display at the control panel or by direct observation;

v. For equipment installed prior to October 1, 1987, the radiation at five centimeters from the filter insertion slot opening does not exceed 30 roentgens per hour under any operating conditions; and

vi. For equipment listed on or after October 1, 1987, the radiation from the filter slot shall not exceed the leakage radiation specified in (a)1 above.

4. A means shall be provided to immobilize the tube housing assembly during stationary treatments;

5. The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within five millimeters, and such marking shall be readily accessible for use during calibration procedures;

6. Equipment employing Beryllium or other low-filtration windows shall have a removable shield of at least 0.5 millimeter lead equivalency at 100 kVp that can be positioned over the entire useful beam exit port during periods when the beam is not in use;

7. Radiotherapy systems of greater than 150 kVp installed on or after October 1, 1987 shall be provided with a beam monitor system which shall:

i. Include a radiation detector which is placed on the patient side of any fixed added filters other than a wedge filter;

ii. Have the radiation detector interlocked to prevent its incorrect positioning in the useful beam;

iii. Not allow irradiation until a pre-selected value of exposure or pre-selected number of dose monitor units has been made at the treatment control panel;

or dose monitor units has been reached;

v. Be so designed that, in the event of a system malfunction or electrical power failure, the dose administered to a patient prior to the system malfunction or power failure can be accurately determined;

vi. Have a display at the control panel, reading in roentgens, or coulombs per kilogram from which the dose at a reference point in the treatment volume can be calculated;

(1) The reading shall be maintained in the display at the control panel until intentionally reset to zero; and

vii. Have a control panel display which does not have scale multiplying factors and utilizes a design such that an increasing dose is displayed by increasing numbers.

8. The following are the equipment requirements for timer systems:

i. A timer system shall be provided which has a display at the treatment control panel. It shall be graduated in minutes and seconds and/or fractions of minutes. It shall have a pre-set time selector. For equipment installed on or after October 1, 1987, it shall also have an elapsed time indicator;

ii. The timer shall terminate irradiation when a pre-selected time has elapsed;

iii. The timer shall permit pre-setting and determination of exposure times to an accuracy of one second or less;

iv. The timer shall not permit an exposure if set at zero;

v. When patient irradiation is controlled by a shutter mechanism the timer shall not begin to run until the shutter is opened;

vi. Equipment installed on or after October 1, 1987 shall have an elapsed-time indicator which is activated when radiation is emitted and retains its reading after irradiation is interrupted or terminated; and

vii. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to cycle the pre-set time selector through zero time.

9. In addition to the control panel displays required in other provisions of this subsection, the control panel shall have:

i. An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;

ii. An indication of whether x-rays are being produced;

iii. Means for indicating kVp and x-ray tube current; and

iv. The means for terminating an exposure at any time.

10. There shall be a means of determining the source-to-patient distance to within 10 percent or one centimeter, whichever is smaller; and

11. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five seconds, the entire useful beam shall be attenuated automatically by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition:

    i. After the unit is at operating parameters, the shutter shall be controlled electrically from the control panel by the operator; and
    ii. An indication of shutter position shall appear at the control panel.

(b) In addition to shielding adequate to meet the requirements of N.J.A.C. 7:28-5 and 6, the treatment room design and shielding requirements for systems capable of operating above 50 kVp, shall be the following:

1. There shall be warning lights in treatment rooms to which access is possible through more than one entrance. The warning lights shall be placed in readily observable positions near the outside of all access doors and shall indicate when the useful beam is "on";

2. There shall be means for two-way aural communication between the patient and the operator at the control panel at all times when the system is in operation;

3. A window, mirror, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel. When the primary viewing system is by electronic means (for example, television), a secondary viewing system shall be available for use in the event of failure of the primary viewing system;

4. Treatment rooms which contain an x-ray system capable of operating above 150 kVp shall meet the following additional requirements:

    i. All required shielding, except for any beam interceptor, shall be provided by fixed barriers;

    ii. The control panel shall be outside the treatment room;

    iii. All entrance doors of the treatment room shall be electrically connected to the control panel in such a way that x-ray production cannot occur unless all doors are closed;

    iv. When any entrance door of the treatment room is opened while the x-ray tube is activated, x-ray production shall terminate within one second; and

    v. After the radiation output of the x-ray tube has been termi-nated by the opening of any door of the treatment room, it shall be possible to restore the x-ray system to full operation only upon closing the door, and subsequently, reinitiating the exposure at the control panel.

(c) The following are the calibration requirements for therapeutic x-ray systems with energies less than one MeV:

1. System calibrations shall be performed before the system is first used for irradiation of a

patient and thereafter at time intervals which do not exceed 12 months and after any change which might significantly alter the calibration or other characteristic of the therapy beam;

2. The calibration of the radiation output of the x-ray system shall be performed by a qualified radiological physicist;

3. Calibration of the radiation output of an x-ray system shall be performed with an instrument whose calibration shall be directly traceable to a national standard and which shall have been calibrated within the preceding three years;

4. The calibration shall be such that the dose at a reference point in soft tissue can be calculated to within +pm 5 percent;

5. The calibration of the x-ray system shall include, but not be limited to, the following determinations;

    i. Verification that the x-ray system is operating in compliance with the radiological design specifications;

    ii. The exposure rates for each combination of field size, technique factors, filter, and treatment distance used;

    iii. The congruence between the radiation field and the field indicated by the localizing device if such device is present; and

    iv. The uniformity of the radiation field symmetry for representative field sizes used.

6. Records of calibration performed pursuant to 1 above shall be maintained by the registrant and made available for inspection by the Department for five years after completion of the calibration.

(d) Spot checks shall be performed on therapeutic x-ray systems with energies greater than 0.018 MeV and less than one MeV and shall meet the following requirements:

1. The qualified radiological physicist will determine those parameters to be spot-checked and the procedure to be used when performing those spot checks. The spot check procedure shall be in writing and specify the frequency at which tests or measurements are to be performed, not to exceed one month, and the acceptable tolerance for each parameter measured in the spot-check. A qualified radiological physicist need not actually perform the spot-check measurement. If a qualified radiological physicist does not perform the spot-check measurement, the results of the spot-check measurement shall be reviewed by a qualified radiological physicist within 15 days;

2. The measurements taken during spot checks shall demonstrate the degree of consistency of the operating characteristics which can affect the radiation output of the system or the radiation delivered to a patient during a therapy procedure;

3. Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the spot check procedures, the system shall be recalibrated;

4. The cause for a parameter exceeding tolerances set by the qualified radiological physicist shall be promptly investigated and corrected before the system is used for patient irradiation; and

5. Records of spot-check measurements shall be maintained by the registrant and made available for inspection by the Department for a period of five years following such measurement.

(e) The following procedures shall be followed when operating therapeutic x-ray systems with energies less than one MeV:

1. A therapeutic x-ray system shall not be left unattended unless the system is secured against unauthorized use;

2. No individual other than the patient shall be in the treatment room unless such individual is protected by a barrier meeting the requirements of N.J.A.C. 7:28-6. No individual other than the patient shall be in the treatment room during exposure when the kVp exceeds 50;
3. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used; and

4. Except for contact therapy devices, the tube housing assembly shall not be held by an individual during exposure.

(f) The x-ray system shall not be used in the administration of radiation therapy unless the requirements of this section have been met.

Correction: Therapeutic x-ray systems with energies less than one MeV for 0-150 kVp systems which are installed prior to October instead of January.
See: 19 N.J.R. 1917(c).

7:28-14.4 Therapeutic x-ray and therapeutic accelerator installations with energies of one MeV and above

(a) The following are the equipment requirements related to leakage radiation to the patient area:

1. Leakage radiation shall be measured under conditions producing maximum leakage radiation and shall be reported as absorbed dose in rads or grays in water. For equipment installed on or after October 1, 1987, measurements shall include x-rays, electrons and neutrons. For equipment incapable of operating at energies greater than 10 MeV, measurements shall exclude neutrons. For equipment installed before October 1, 1987, measurements shall exclude neutrons. The leakage radiation shall be measured in a plane perpendicular to the central axis of the beam located at the normal treatment distance or passing through the isocenter. The leakage radiation at any point on this plane outside the useful beam but within two meters of the central axis of the beam shall not exceed 0.1 percent of the maximum radiation of the useful beam, measured at the point of intersection of the central axis and the plane;

2. Measurements for leakage radiation shall be averaged over an area up to, but not exceeding, 100 square centimeters at the positions specified. For equipment installed on or after October 1, 1987, measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to, but not exceeding, 400 square centimeters. For equipment incapable of operating at energies greater than 10 MeV, measurements shall exclude neutrons. For equipment installed before October 1, 1987, measurements shall exclude neutrons;

3. For each system the registrant shall determine, or obtain from the manufacturer, the amount of leakage radiation at the positions specified in 1 above. Records of leakage radiation shall be maintained at the facility for inspection by the Department.

(b) The following are the equipment requirements for leakage radiation outside the patient area:

1. Except in the area specified in (a) above as the patient area, the x-ray leakage measured as absorbed dose in rads or grays in water, at any location averaged over 100 square centimeters one meter from the path of the charged particles before they strike the target or the window, shall not exceed 0.1 percent of the maximum absorbed dose in the circular plane specified in (a) above;

2. Except in the area specified in (a) above as the patient area, neutron leakage measured as absorbed dose in rads or grays in water, at any point one meter from the path of the charged particles before they strike the target or the window, shall not exceed 0.5 percent of the maximum absorbed dose in the circular plane specified in (a) above;

3. The registrant shall determine, or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in 1 and 2 above for specified operating conditions. Radiation measurements excluding neutrons shall be averaged over an area up to, but not exceeding, 100 square centimeters at the positions specified. For equipment installed on or after October 1, 1987, neutron measurement shall be averaged over an area up to, but not exceeding, 400 square centimeters. For equipment incapable of operating at energies greater than 10 MeV, measurements shall include neutrons. For equipment installed prior to October 1, 1987, measurement of neutrons shall be excluded.

(c) The following are the equipment requirements for beam limiting devices:

1. For equipment installed on or after October 1, 1987, adjustable or interchangeable beam limiting devices shall be provided and such devices shall transmit no more than one percent of the useful beam at the normal treatment distance for the portion of the useful beam which is to be attenuated by the beam limiting device. The neutron component of the useful beam shall not be included in this requirement; and

2. For equipment installed prior to October 1, 1987, the beam limiting device shall meet the requirements of (a)1 above except that such device shall transmit no more than two percent of the useful beam.

(d) The following are the equipment requirements for filters:

1. If the absorbed dose rate information required by (p) below relates exclusively to operation with a field flattening or beam scattering filter in place, such filter shall be removable only by the use of tools;

2. In systems installed on or after October 1, 1987, which utilize a system of wedge filters, interchangeable field flattening filters or interchangeable beam scattering filters:

   i. Irradiation shall not be possible until a selection of a filter has been made at the treatment control panel;

   ii. An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;

   iii. A display shall be provided at the treatment control panel showing the filter in use;

   iv. Each filter which is removable from the system without the use of tools shall be clearly marked with an identification number and accompanying documents shall contain a corresponding drawing or other description of the filter, showing dimensions and

materials. The identification number shall appear on the wedge filter as well as on its tray. The identification number shall be referable to wedge angle and wedge factor; and

v. An interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.

3. The only filter requirement for equipment installed prior to October 1, 1987 shall be that required by (d)2iv above.

(e) Beam quality data sufficient to assure that the following beam quality requirements are met shall be determined or obtained from the manufacturer by the registrant:

1. For radiotherapy systems capable of electron beam therapy the absorbed dose in water resulting from x-rays in a useful electron beam shall be determined at a point on the central axis of the beam 10 centimeters greater than the practical range of the electrons. This shall not exceed the values stated in the following table. Linear interpolation shall be used for values not stated;

TABLE

# Maximum Energy of Electron Beam in MeV	X-Ray absorbed Dose as a Fraction of Maximum Absorbed Dose
1	0.03
15	0.05
35	0.10
50	0.20

2. Compliance with 1 above shall be determined using:

i. A measurement within a phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam;
ii. The largest field size available which does not exceed 15 centimeters by 15 centimeters; and
iii. A phantom whose cross-sectional dimensions exceed the measurement radiation field by at least five centimeters and whose depth is sufficient to perform the required measurement.

3. The absorbed dose at a surface located at the normal treatment distance, at the point of intersection of that surface with the central axis of the useful beam during x-ray irradiation, shall be measured at intervals not to exceed 12 months and the results of such measurements shall be maintained with the records of calibration;

4. The measurements required by (e)3 above shall conform to the following requirements:

i. Measurements shall be made within a phantom using an instrument which will allow extrapolation to the surface absorbed dose;

ii. Measurements shall be made using a phantom whose size and placement meet the requirements of 2iii above;

iii. Measurements shall be made after removal of all beam modifying devices which can be removed without the use of tools, except for beam scattering or beam flattening filters; and

iv. Measurements shall be made over the range of field sizes clinically used.

5. The registrant shall determine, or obtain from the manufacturer, the maximum percentage absorbed dose due to stray neutrons in the useful beam for specified operating conditions.

(f) All therapy systems shall be provided with radiation detectors in the radiation head.

1. Equipment installed on or after October 1, 1987 shall be provided with at least two radiation detectors. The detectors shall be incorporated into two monitoring systems arranged either as a primary/primary combination or as a primary/secondary combination;

2. Equipment installed prior to October 1, 1987 shall be provided with at least one radiation detector. This detector shall be incorporated into a primary system. Failure of this detector shall automatically cause the beam to be terminated; and

3. Each detector and system into which the detector is incorporated shall meet the following requirements:

i. Each detector shall be removable only with tools and shall be interlocked to prevent incorrect positioning;

ii. Each detector shall be capable of independently monitoring and controlling the useful beam;

iii. Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated;

iv. For equipment installed on or after October 1, 1987, the primary dose monitoring system shall have a full beam transmission detector which is placed on the patient side of any fixed added filters other than a wedge filter;

v. For equipment installed on or after October 1, 1987, the design of the dose monitoring system of (f)3iii above shall assure that:

(1) The malfunctioning of one system shall not affect the correct functioning of the second system; and

(2) The failure of any element which may be common to both systems shall terminate the useful beam.

vi. Each dose monitoring system shall have a legible display at the treatment control panel. Each display shall:

(1) Maintain a reading until intentionally reset to zero;

(2) Utilize a design such that increasing dose is displayed by increasing numbers and shall be so designed that, in the event of an overdosage of radiation, the absorbed dose may be accurately determined under all normal conditions of use or foreseeable failures; and

(3) In equipment installed on or after October 1, 1987 have only one scale and no scale multiplying factors when employed for routine therapy. A scale multiplying factor may be applied to the regularly used accumulated dose indicator when used in conjunction with special treatment modes which use higher than normal dose rates and require specially safeguarded operating procedures to initiate.

vii. In the event of power failure, the dose monitoring information required in 3vi above displayed at the control panel at the time of failure shall be retrievable in at least one system.

(g) Beam symmetry requirements are the following:

1. For equipment installed on or after October 1, 1987 and which is inherently capable of producing useful beams with asymmetry exceeding five percent, at least four different parts of the radiation beam shall be monitored before the beam passes through the beam limiting device. If the difference in dose rates between any two of these different parts exceeds five percent an indication of this condition is to be made at the control panel and the irradiation shall automatically terminate; and

2. The beam symmetry requirements of 1 above shall be met if the user can demonstrate to the satisfaction of the Department that adequate fail-safe protection against the beam asymmetry is incorporated into the inherent design of the accelerator.

(h) Equipment requirements for the selection and display of dose monitor units are the following:

1. Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel;

2. The pre-selected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation; and

3. After termination of irradiation, it shall be necessary to manually cycle the pre-selected dose monitor units through zero or manually change at least one digit on the dose monitor units selector before treatment can be initiated.

(i) Equipment requirements for termination of irradiation by the dose monitoring system are the following:

1. Each of the required monitoring systems shall be capable of terminating irradiation independently;

2. Each primary dose monitoring system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system;

3. Each secondary dose monitoring system shall terminate irradiation when 10 percent or 30 monitor units above the pre-selected number of dose monitor units has been detected by the system;

4. For equipment installed on or after October 1, 1987, the indicator on the control panel shall show which monitoring system has terminated the beam.

(j) Interruption switches shall be provided which make it possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel.

Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption the equipment shall go to termination condition.

(k) Termination switches shall be provided at the operator's position at the treatment control panel, which make it possible to terminate irradiation and equipment movements, or to go from an interruption condition to termination condition.

(l) The following are the equipment requirements for timer systems:

1. A timer system shall be provided which has a display at the treatment control panel. It shall be graduated in minutes and seconds and/or fractions of minutes. It shall have a pre-set time selector and an elapsed time indicator;

2. The timer shall terminate irradiation when a pre-selected time has elapsed if the dose monitoring systems fail to do so;

3. The timer shall not permit an exposure if set at zero;

4. There shall be an elapsed-time indicator which is activated when radiation is emitted and which retains its reading after irradiation is interrupted or terminated; and

5. After termination of irradiation on delivery of the present dose, it shall be necessary to manually change at least one digit on the pre-set time control before treatment can be re-initiated.

(m) Equipment capable of both x-ray therapy and electron therapy shall have the following equipment requirements for selection of radiation type:

1. Irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel;

2. An interlock system shall be provided to insure that the equipment can emit only the radiation type which has been selected, except as noted in 4 below;

3. An interlock system shall be provided to prevent irradiation if any operations selected in the treatment room do not agree with the operations selected at the treatment control panel;

4. An interlock system shall be provided to prevent irradiation with x-rays when electron applicators are fitted except to obtain a port film and to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted; and

5. The radiation type selected shall be displayed at the treatment control panel before and during irradiation.

(n) The following are the equipment requirements for the selection of energy for equipment capable of generating radiation beams of different energies:

1. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;

2. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the

treatment control panel;

3. The nominal energy selected shall be displayed at the treatment control panel before and during irradiation; and

4. For equipment installed on or after October 1, 1987, an interlock system shall be provided to terminate irradiation if the energy of the electrons striking the x-ray target or electron window deviates by more than plus or minus five percent or plus or minus 2 MeV, whichever is smaller, from the selected nominal energy.

(o) The following are the equipment requirements for selection of mode of therapy for equipment capable of both stationary beam therapy and moving beam therapy:

1. Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel;

2. An interlock system shall be provided to insure that the equipment can operate only in the mode which has been selected;

3. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel;

4. An interlock system shall be provided to interrupt irradiation if the movement stops during moving beam therapy;

5. Moving beam therapy shall be so controlled that the required relationship between the number of dose monitor units and movement is obtained; and

6. The mode of operation shall be displayed at the treatment control panel.

(p) Equipment installed on or after October 1, 1987, shall be provided with a system from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated. The radiation detectors specified in (f) above may form part of this system. In addition, the quotient of the number of dose monitor units by time shall be displayed at the treatment control panel.

(q) The registrant shall determine, or obtain from the manufacturer, the location of the following with reference to an accessible point on the radiation head and under all possible orientations of the useful beam:

1. The x-ray target or the virtual source of x-rays; and
2. The electron window, the scattering foil, or the virtual source of electrons.

(r) When pre-selection of any of the operating conditions requires action in the treatment room and at the treatment control panel, selection at one location shall not give a display at the other location until the requisite selected operations in both locations have been completed.

(s) Shadow trays shall be designed to minimize patient entrance skin dose consistent with achieving their primary purpose of safely supporting beam-modifying accessories while transmitting the light field.

(t) The following are the facility and shielding requirements for therapeutic x-ray and therapeutic accelerator installations with energies of one MeV and above:

1. The systems shall have shielding adequate to meet the requirements of N.J.A.C. 7:28-5 and 6;

2. Except for entrance doors or beam interceptors, all the required barriers shall be fixed barriers;

3. The treatment control panel shall be located outside the treatment room;

4. Windows, mirrors, closed-circuit television, or other equivalent viewing systems shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. When the primary viewing system is by electronic means (for example, television), a secondary viewing system shall be provided for use in the event of failure of the primary system;

5. Provision shall be made for two-day aural communication between the patient and the operator at the treatment control panel;

6. Treatment room entrances shall be provided with warning lights in readily observable positions near the outside of all access doors which will indicate when the useful beam is "on";

7. Interlocks shall be provided such that all entrance doors shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall only be possible to restore the machine to operation by closing the door and reinitiating exposure by manual action at the control panel; and

8. At least one "Panic" emergency shut-off button shall be located in the treatment room and one by the control panel. The "Panic" button shall be clearly visible, easily accessible and be capable of immediately terminating machine operation.

(u) The following are the calibration requirements for therapeutic x-ray and therapeutic accelerator installations with energies of one MeV and above:

1. The calibration of systems shall be performed before the system is first used for irradiation of a patient, and thereafter at time intervals which do not exceed 12 months and after any change which might, in the opinion of the qualified radiological physicist, significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam;

2. The calibration shall be performed with an established calibration protocol which meets or exceeds the requirements set by the American Association of Physicists in Medicine;

3. The calibration shall be performed by a qualified radiological physicist;

4. The calibration shall be performed with a dosimetry system whose calibration shall be directly traceable to a national standard and which shall have been calibrated within the preceding three years;

5. The calibration shall be such that the dose at a reference point in soft tissue may be calculated within plus or minus 5 percent;

6. The full calibration of the therapy beam shall include, but not be limited to, the following determinations:

i. Verification that the equipment is operating in compliance with the design specifications for accuracy of the light localizer, the side light and backpointer alignment with the isocenter;

ii. Verification that the equipment is operating in compliance with the design specifications for acceptable variation in the axis of rotation for the table, gantry and jaw system, and beam flatness and symmetry at specified depths;

iii. The absorbed dose rate at representative depths in a phantom for the range of field sizes used for each effective energy, and for representative distances used for radiation therapy;

iv. The congruence between the radiation field and the field indicated by the localizing device;

v. The uniformity of the radiation field and its dependency upon the direction of the useful beam;

vi. Verification of depth-dose data and isodose curves applicable to the specific machine; and

vii. Verification of the applicability and transmission factors of all accessories such as wedges, shadow trays, compensators, etc.

7. Records of the calibration performed pursuant to 1 above shall be maintained by the registrant and made available for inspection by the Department for five years after completion of the calibration; and

8. A copy of the latest full calibration shall be available for calculating patient treatment parameters.

(v) Spot checks meeting the following requirements shall be performed on all therapeutic x-ray and therapeutic accelerator installations with energies of one MeV and above:

1. The qualified radiological physicist will determine those parameters to be spot-checked and the procedure to be used when performing those spot checks. The spot-check procedure shall be in writing and shall specify the frequency at which tests or measurements are to be performed, not to exceed one month, and the acceptable tolerance for each parameter measured in the spot-check. A qualified radiological physicist need not actually perform the spot-check measurement. If a qualified radiological physicist does not perform the spot-check measurement, the results of the spot-check measurement shall be reviewed by a qualified radiological physicist within 15 days;

2. The measurements taken during spot-checks shall demonstrate the degree of consistency of the operating characteristics which can affect the radiation output of the system or the radiation delivered to a patient during a therapy procedure;

3. The cause for a parameter exceeding tolerances set by the qualified radiological physicist shall be promptly investigated and corrected before the system is used for patient irradiation;

4. Whenever a spot-check indicates a significant change in the operating characteristics of a system, as specified in the spot-check procedures, the system shall be recalibrated as required in (u) above; and

5. Records of spot-check measurements performed shall be maintained by the registrant for a period of five years and made available for inspection by the Department.

(w) Operating procedures for therapeutic x-ray and therapeutic accelerator installations with energies of one MeV and above are as follows:

1. Therapeutic systems shall not be left unattended unless the system is secured against unauthorized use;

2. No individual other than the patient shall be in the treatment room during treatment of a patient;

3. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used; and

4. The system shall not be used in the administration of radiation therapy unless the requirements of (u) and (v) above have been met.

SUBCHAPTER 15. MEDICAL DIAGNOSTIC X-RAY INSTALLATIONS15. MEDICAL DIAGNOSTIC X-RAY INSTALLATIONS

7:28-15.1 Scope

(a) This subchapter establishes the requirements for medical radiographic and fluoroscopic installations of certified and uncertified ionizing-radiation-producing machines used in all the healing arts, except where exempted by the rules in N.J.A.C. 7:28-16, Dental Radiographic Installations.

(b) No person shall operate or permit the operation of x-ray equipment used in the healing arts unless the equipment and installation meet the applicable requirements of this subchapter.

(c) Provisions of this subchapter are in addition to and not in substitution for the applicable provisions of N.J.A.C. 7:28.

(d) The registrant shall ensure that all ionizing-radiation-producing machines under his or her jurisdiction are operated only by persons authorized pursuant to the Radiologic Technologist Act, N.J.S.A. 26:2D-24 through 36, and applicable provisions of N.J.A.C. 7:28-19.

7:28-15.2 Definitions

The words and terms listed below, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.

"Acquired date" means the date the unit has been installed and is capable of use on patients.

"Aluminum equivalent" means the thickness of aluminum (type 1100 alloy) affording the same attenuation, under specified conditions, as the material in question.

"Anti-collision device" means either an electronic position sensor combined with a microprocessor or a mechanical touch bar microswitch which will stop all equipment movement and radiation exposures to prevent collision of any part of the radiation therapy simulator system with the patient, or damage to other components of the simulator system.

"Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into a diagnostic x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

"Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain a required quantity of radiation at a preselected location(s) (for example, phototimer).

"Beam axis" means a line from the source through the center of the x-ray field.

"Beam-limiting device" means a mechanism which provides a means to restrict the dimensions of the x-ray field.

"C-arm x-ray system" means an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

"Cassette holder" means a device, other than a spot-film device, that supports and/or fixes the position of an image receptor during an x-ray exposure.

"Certified components" means components of x-ray systems which are subject to the regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968, 21 Code of Federal Regulations, Chapter 1, Subchapter J, Radiological Health, (21 C.F.R. Part 1020 et seq., Performance Standards for Ionizing Radiation Emitting Products).

"Certified system" means any x-ray system which has all certified components. Also known as a certified unit or a certified diagnostic x-ray system.

"Coefficient of variation" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{X}} = \frac{1}{\bar{X}} \left[\frac{\sum_{i=1}^{n} (X_i - \bar{X})^2}{n-1} \right]^{1/2}$$

where:

s = estimated standard deviation of population
$\bar{X}$ = mean value of observations in sample
X_i = ith observation in sample
n = number of observations in sample

"Computed tomography " (CT) means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

"Computed tomography dose index" (CTDI) means the integral of the dose measured along a line perpendicular to and centered at the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$CTDI = \frac{1}{nT} \int_{-7T}^{+7T} D(z)\, dz$$

where:

z = position along a line perpendicular to the tomographic plane

D(z) = Dose at position z

T = nominal tomographic section thickness

n = number of tomograms produced in a single scan

This definition assumes that the dose profile is centered around z=0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

"Contrast scale" (CS) for computed tomography means the change in the linear attenuation coefficient per CT number relative to water, that is:

$$CS = \frac{ux - uw}{(CT)x - (CT)w}$$

where:

ux = linear attenuation coefficient of material of interest

uw = linear attenuation coefficient of water

(CT)x = CT number of the material of interest

(CT)w = CT number of water

"Contrast ratio" for a light field is the ratio of the illumination three millimeters from the edge of the field towards the center of the field to the illumination three millimeters from the edge of the field away from the center of the field.

"Control panel" means the part of the x-ray control upon which are mounted the switches, knobs, push-buttons, and other hardware necessary for manually setting the technique factors.

"CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system, including nominal tomographic section thickness, filtration, and the technique factors.

"CT number" means the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

"Dedicated mammography unit" means an x-ray system specifically designed for mammographic procedures.

"Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

"Diagnostic type protective tube housing" means an x-ray tube housing so constructed that the leakage radiation at a distance of one meter from the target cannot exceed 100 milliroentgens in one hour when the tube is operated at its maximum continuous rated current for the maximum continuous rated tube potential.

"Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnostic imaging or measurement.

"Emergency off switch" means a switch located near the table or near the console which, when operated, turns off all power to the system.

"Entrance exposure rate" means the exposure per unit time at the point where the center of the useful

beam enters the patient.

"Equipment" means x-ray equipment.

"Exposure" means a measure of the quantity of x or gamma radiation based upon its ability to ionize air through which it passes.

"Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

"Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a fluoroscopic image. The subsystem includes the image intensifier, spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

"General purpose radiographic x-ray system" means any radiographic x-ray system which is not limited by its design to the radiographic examination of a specific anatomical region.

"Half-value layer" (HVL) means the thickness of specified material which attenuates the x-ray beam so that the exposure is reduced to one-half of its original value.

"Image intensifier" means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image.

"Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations. In those cases where means are provided to preselect a portion of the image receptor, the term "image receptor" shall mean the preselected portion of the device.

"Image receptor support" means that part of the system designed to support the image receptor during a radiographic examination.

"kV" means kilovolts.

"kVp" (see "peak tube potential").

"Leakage radiation" means radiation emanating from the diagnostic source assembly except for the useful beam and radiation produced when the exposure switch or timer is not activated.

"Leakage technique factors" means the technique factors associated with the diagnostic source assembly which are used in measuring leakage radiation. They are defined as follows:

1. For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, that is, 10 milliampere seconds (mAs) or the minimum obtainable from the unit, whichever is larger.
2. For diagnostic source assemblies intended for field emission equipment rated for pulsed operations, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.
3. For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

"Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to the plane of the image receptor as well as at the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

"mA" means milliampere.

"mAs" means milliampere second.

"Mobile x-ray equipment" means completely assembled x-ray equipment, which is mounted on a

permanent base with wheels and/or casters and is used in multiple locations.

"Motor vehicle mounted" means an x-ray system permanently mounted and operated in a motor vehicle.

"Multiple-tube installation" means a radiographic installation in which one control panel may energize more than one radiographic x-ray tube.

"Noise" for computed tomography means the standard deviation of the fluctuations in CT number expressed as a percent of the attenuation coefficient of water. Its estimate (S n) is calculated using the following expression:

$$Sn = \frac{100 \times CS \times s}{uw}$$

where: CS = contrast scale
uw = linear attenuation coefficient of water
s = estimated standard deviation of the CT numbers of picture elements in a specified aread of the CT image

"Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which x-ray transmission data are collected.

"Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

"Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

"Positive beam-limiting device" (PBL) means a device which automatically restricts the x-ray field to the size of the image receptor.

"Portable x-ray equipment" means x-ray equipment designed to be hand-carried.

"Primary protective barrier" see "protective barrier"

"Protective barrier" means a barrier of radiation-absorbing material used to reduce radiation exposure. The types of protective barriers are as follows:

1. "Primary protective barrier" means the material, excluding filters, intercepting the useful beam for protection purposes to reduce the radiation exposure so that it does not exceed two millirems in any one hour; and

2. "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to reduce radiation exposure so that it does not exceed two millirems in any one hour.

"Qualified individual for the performance of radiation surveys for diagnostic x-ray equipment and therapy simulator systems" as required in this subchapter means an individual who meets at least one of the following criteria:

1. Certification by one of the following agencies in the specialty listed:

    i. The American Board of Radiology in Diagnostic Radiological Physics or Radiological Physics;

    ii. The American Board of Health Physics in Comprehensive Health Physics;

iii. The American Board of Medical Physics in Diagnostic Imaging Physics or Medical Health Physics;

iv. Certification issued by the Fellowship in the Canadian College of Physicists in Medicine which is equivalent to 1i or iii above; or

v. Certification by other national certifying boards which may be recognized by the Commission on Radiation Protection (Commission) where the person seeking recognition as a qualified individual for the performance of radiation surveys for diagnostic x-ray equipment and therapy simulator systems has petitioned the Commission in writing and where the Commission has issued a written determination that the certification in question meets the criteria of a qualified individual pursuant to this definition;

2. A bachelor's degree from an accredited college in biology, chemistry, radiation sciences, physics, engineering, or mathematics and at least five years of professional technical experience in the field of radiological physics or in the use of medical ionizing-radiation-producing equipment;

3. A master's or doctorate degree from an accredited college in radiological health, radiation sciences, physics, chemistry, environmental sciences, engineering or a related field and at least two years of professional technical experience in the field of radiological physics or in the use of medical ionizing-radiation-producing equipment;

4. Ten years of professional technical experience in the field of radiological physics or in a radiation protection activity. At least five years of the required health physics experience shall have been with medical ionizing-radiation-producing equipment; or

5. Any individual who does not meet at least one of the foregoing criteria may petition the Commission for recognition as a "qualified individual for the performance of radiation surveys for diagnostic x-ray equipment and therapy simulator systems". The individual shall submit a written petition to the Commission which contains sufficient information on his or her educational, professional, clinical, technical, employment and/or any other relevant experience. The Commission may approve any such petition based on its determination that the individual demonstrates competence to act as a qualified individual for the performance of radiation surveys for diagnostic x-ray equipment and therapy simulator systems.

"Qualified medical physicist for the supervision of quality assurance programs for diagnostic x-ray equipment" as required in this subchapter means an individual who meets at least one of the following criteria:

1. Certification by one of the following agencies in the specialty listed:

i. The American Board of Radiology in Diagnostic Radiological Physics or Radiological Physics;

ii. The American Board of Medical Physics in Diagnostic Imaging Physics;

iii. Certification issued by the Fellowship in the Canadian College of Physicists in Medicine which is equivalent to 1i. or ii. above; or

iv. Certification by other national certifying boards which may be recognized by the Commission where the person seeking recognition as a qualified medical physicist for

the supervision of quality assurance programs for diagnostic x-ray equipment has petitioned the Commission in writing and where the Commission has issued a written determination that the certification in question meets the criteria of a qualified medical physicist pursuant to this definition;

2. A master's or doctorate degree from an accredited college in radiological health, radiation sciences, physics, chemistry, environmental sciences, engineering or a related field and at least three years of professional, clinical and technical experience in the field of radiological physics obtained under the supervision of a qualified medical physicist for the supervision of quality assurance programs for diagnostic x-ray equipment; or

3. Any individual who does not meet at least one of the foregoing criteria may petition the Commission for recognition as a qualified medical physicist for the supervision of quality assurance programs for diagnostic x-ray equipment. The individual shall submit a written petition to the Commission which contains sufficient information on his or her educational, professional, clinical, technical, employment and/or any other relevant experience. The Commission may approve any such petition based on its determination that the individual demonstrates competence to act as a qualified medical physicist for the supervision of quality assurance programs for diagnostic x-ray equipment.

"Qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems" means an individual who meets at least one of the criteria listed below:

1. Is certified by the American Board of Radiology in Therapeutic Radiological Physics or by the American Board of Medical Physics with special competency in radiation oncology physics;

2. Is certified by the American Board of Radiology in Radiological Physics which includes all three subspecialties of diagnostic radiological physics, therapeutic adiological physics, and medical nuclear physics;

3. Is certified by the American Board of Radiology or the American Board of Medical Physics in a specialty other than therapeutic radiological physics or radiation oncology physics and has at least three years of professional, clinical and technical experience obtained under the supervision of a qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems;

4. Certification issued by the Fellowship in the Canadian College of Physicists in Medicine which is equivalent to 1, 2, or 3 above;

5. Certification by other national certifying boards which may be recognized by the Commission where the person seeking recognition as a qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems has petitioned the Commission in writing and where the Commission has issued a written determination that the certification in question meets the criteria of a qualified medical physicist pursuant to this definition;

6. A master's or doctorate degree from an accredited college in radiological health, radiation sciences, physics, chemistry, environmental sciences, engineering or a related field and at least three years of professional, clinical and technical experience in the field of radiological physics obtained under the supervision of a qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems; or

7. Any individual who does not meet at least one of the foregoing criteria may petition the

Commission for recognition as a qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems. The individual shall submit a written petition to the Commission which contains sufficient information on his or her educational, professional, clinical, technical, employment and/or any other relevant experience. The Commission may approve any such petition based on its determination that the individual demonstrates competence to act as a qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems.

"Quality assurance" means an organized effort by the registrant to maintain a level of equipment performance to assure consistent production of diagnostic images without unnecessary radiation exposure. It includes quality control procedures and administrative procedures.

"Quality control" is the routine measurement of image quality and the performance of the diagnostic x-ray imaging system, from x-ray beam output to the viewing of radiographs, and the continual adjustment of that performance to an optimal and consistent level.

"Radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

"Radiograph" means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

"Radiographic imaging system" means any system whereby a permanent or temporary image is recorded on an image receptor by the action of ionizing radiation.

"Reference plane" for computed tomography means a plane which is displaced from and parallel to the tomographic plane.

"Registrant" means a person who is required to register a source of radiation with the Department pursuant to this chapter.

"Scan" for computed tomography means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

"Scan increment" for computed tomography means the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

"Scan time" means the period of time between the beginning and end of photon transmission data accumulation for a single scan.

"Scan sequence" for computed tomography means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

"Scattered radiation" means radiation that, during passage through matter, has changed in direction or in energy.

"Sensitivity profile" means the relative response of the CT x-ray system as a function of position along a line perpendicular to the tomographic plane.

"Single-purpose x-ray system" means an x-ray system which is limited by its design to the radiological examination of a specific anatomical region.

"Source" means the focal spot of the x-ray tube.

"Source-to-image receptor distance" (SID) means the distance from the source to the center of the input surface of the image receptor.

"Source-to-skin distance" (SSD) means the distance from the source of radiation to the patient's skin.

"Spot-film device" means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

"Stationary equipment" means equipment which is installed in a fixed location.

"Technique factors" means the conditions of operation of a diagnostic x-ray system. They are specified as follows:

1. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs.

2. For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses.

3. For computed tomography x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs.

4. For computed tomography x-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time in seconds when the scan time in seconds and the exposure time are equivalent.

5. For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

"Tomogram" means an image of a planar section of a body part or object.

"Tomographic plane" for computed tomography means that geometric plane which is identified as corresponding to the tomographic image.

"Tomographic section" for computed tomography means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

"Tube housing assembly" means the x-ray tube housing with the x-ray tube insert installed. It includes high-voltage and/or filament transformers and other components that are contained within the tube housing.

"Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

"Uncertified unit" means an x-ray system comprised of components that are not subject to the regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968, 21 Code of Federal Regulations, Chapter 1, Subchapter J Radiological Health, (21 C.F.R. Part 1020 et seq., Performance Standards for Ionizing Radiation Emitting Products). An "uncertified unit" is also known as a noncertified unit or a noncertified diagnostic x-ray system.

"Useful beam" means the radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

"Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

"Xeromammography" means the recording of an x-ray image of the breast using a uniformly charged photoconductive (selenium alloy) plate held in a light-proof cassette instead of using conventional x-ray film.

"X-ray control" means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness control systems (stabilizers), and similar devices or means, which control the technique factors of an x-ray exposure.

"X-ray equipment" means an x-ray system, subsystem, or component thereof.

"X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

"X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the x-ray control to the x-ray tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

"X-ray system" means an assembly of components for the controlled production of x-rays. The system includes an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

"X-ray subsystem" means any combination of two or more components of an x-ray system.

"X-ray tube" means any electron tube which is designed for the conversion of electrical energy into x-ray energy.

7:28-15.3 General requirements for radiographic installations

(a) The provisions of this section are in addition to and not in substitution for the applicable provisions of N.J.A.C. 7:28.

(b) No person shall operate or permit the operation of any certified or uncertified radiographic x-ray equipment used in the healing arts unless a diagnostic type protective tube housing is provided.

(c) No person shall operate or permit the operation of any certified or uncertified radiographic x-ray equipment used in the healing arts unless a device is used to collimate the useful beam, and this device provides the same degree of protection as required of the diagnostic type protective tube housing.

1. Any new or used x-ray machine sold or otherwise transferred after July 1, 1969 shall be equipped with an adjustable, rectangular collimator fitted with a light field or laser system for delineating the edges of the collimated x-ray beam. The light field and/or laser system shall be operational. There shall be provided a means for stepless adjustment of the size of the x-ray field. The minimum field size at an SID of 100 centimeters (39.4 inches) shall be equal to or less than five centimeters by five centimeters (two inches by two inches). For equipment that employs a light field to define the x-ray field, the following criteria shall apply:

i. The light field shall have an average illumination of not less than 160 lux (15 footcandles) at 100 centimeters (39.4 inches) or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are exempt from this requirement.

ii. The edge of the light field at 100 centimeters (39.4 inches) or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than four for beam-limiting devices designed for use on stationary equipment, and a

contrast ratio of not less than three for beam-limiting devices designed for use on mobile and portable equipment.

iii. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed two percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

iv. If a laser system is used to delineate the edges of the collimated x-ray beam, this source shall provide illumination levels sufficient to determine the collimated edges under ambient light conditions.

2. A system not requiring a light-beam collimator shall have an assortment of removable, fixed-aperture, beam-limiting devices (diaphragms) sufficient to meet each combination of image receptor size and SID used. Each fixed-aperture beam-limiting device shall be clearly and permanently marked to indicate the image receptor size and SID for which it is designed. Each fixed-aperture beam-limiting device shall limit the size of the x-ray field to the size of the image receptor. It shall be the responsibility of the operator to ensure that the correct combination of diaphragm and image receptor size is used during the radiographic procedure.

3. A single-purpose x-ray system, such as chest x-ray equipment, may use a fixed collimator provided the x-ray field does not exceed the size of the image receptor and the beam is fully intercepted by the image receptor. If such an x-ray system is equipped with a light field system, it shall be exempt from (c) 1 above.

(d) No person shall operate or permit the operation of any certified or uncertified radiographic x-ray equipment used in the healing arts unless the beam alignment and distance measurements meet the following requirements:

1. Certified x-ray systems shall be provided with a means or device to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor;

2. The center of the x-ray field shall be aligned with respect to the center of the image receptor to within two percent of the SID when the x-ray beam is perpendicular to the plane of the image receptor; and

3. A means shall be provided to indicate the SID to within two percent. If it is a fixed SID, the distance shall be indicated on the unit with a permanent marking.

(e) No person shall operate or permit the operation of any certified or uncertified radiographic x-ray equipment used in the healing arts unless the x-ray filtration and beam quality meet the following requirements:

1. The amount of total filtration permanently in the useful beam shall provide the minimum half-value layer specified in the following table:

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TABLE 11

TABLE OF HALF VALUE LAYERSOF HALF VALUE LAYERS

Measured	Minimum

Designed Operating Range (kVp)	operating potential (kVp)	half-value layer(HVL) (mm of Al)
Below 51	30	0.3
	40	0.4
	50	0.5
51 to 70	51	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

(f) No person shall operate or permit the operation of any certified or uncertified radiographic x-ray equipment used in the healing arts unless the exposure control and exposure timer meet the following requirements:

1. A device shall be provided to terminate the exposure at a preset time interval, preset product of current and time, preset number of pulses, or preset radiation exposure;

    i. Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure greater than one-half second;

    ii. Except during serial radiography, termination of the exposure shall cause automatic resetting of the timer to its initial setting or to zero;

    iii. Except during serial radiography, it shall not be possible to make an exposure when the timer is set to a zero or off position, if either position is provided;

    iv. During serial radiography, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process;

2. The x-ray control panel shall include a means for indicating x-ray tube voltage (kVp), tube current (mA), and time setting or the product of the tube current and time setting in milliampere-seconds (mAs);

3. The x-ray control panel shall provide visual indication to the operator whenever x-rays are produced. Certified equipment shall also provide audible indication to the operator while x-rays are produced or on termination of the exposure;

4. The technique factors to be used during an exposure shall be indicated on the control panel before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated. For equipment having fixed technique factors, this requirement shall be met by permanent markings;

5. The exposure control switch when depressed shall not energize the x-ray tube when the timer is in the “off” or “zero” position;

6. The exposure control switch shall be arranged so that it can only be operated when the

operator is within a shielded area;

7. For equipment that provides an automatic exposure control, the following requirements shall be met:

    i. There shall be a device on the control panel that indicates when this mode of operation is selected;

    ii. For certified equipment only, a signal audible and visible to the operator shall indicate when an exposure has been terminated; or

    iii. For uncertified equipment only, a signal visible to the operator shall indicate when the exposure has terminated;

(g) No person shall operate or permit the operation of any certified or uncertified radiographic x-ray equipment used in the healing arts unless the accuracy, reproducibility and linearity meet the following requirements:

1. The timer accuracy shall not exceed the limits specified by the manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10 percent of the indicated value;

2. The following timer reproducibility requirements shall apply:

    i. For certified equipment only, the coefficient of variation of the timer reproducibility shall not exceed 0.05 for any specific combination of selected technique factors.

    ii. For uncertified equipment only, the coefficient of variation of the timer reproducibility shall not exceed 0.07 for any specific combination of selected technique factors;

3. The following exposure reproducibility requirements shall apply:

    i. For certified equipment only, the coefficient of variation of radiation exposure reproducibility shall not exceed 0.05 for any specific combination of selected technique factors.

    ii. For uncertified equipment only, the coefficient of variation of radiation exposure reproducibility shall not exceed 0.07 for any specific combination of selected technique factors;

4. The kVp accuracy shall not exceed the limits specified by the manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10 percent of the indicated value;

5. The kVp reproducibility shall not exceed a coefficient of variation of 0.05; and

6. The following linearity requirements apply to x-ray equipment which allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rating.

    i. For x-ray equipment having independent selection of x-ray tube current (mA), the average ratios of exposure to the indicated milliampere-seconds product (mR/mAs) or

(C/kg/mAs) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum.

ii. For equipment manufactured after May 3, 1994, x-ray equipment having a combined x-ray tube current-exposure time product (mAs) selector, the average ratios of exposure to the indicated milliampere-seconds product (mR/mAs) or (C/kg/mAs) values obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum.

iii. The average exposure ratio for 15.3(g) 6i and ii above shall be expressed as follows:

$| X1 - X2 | \leq 0.10 (X1 + X2)$
where X1 and X2 are the average mR/mAs or C/kg/mAs
values obtained at each of two consecutive tube mA or mAs settings.

(h) No person shall operate or permit the operation of a certified or uncertified multiple-tube installation where a control panel can energize more than one x-ray tube unless the following additional requirements are met: (Interventional biplane radiographic systems shall be exempted from these additional requirements.)

1. Only one radiographic tube shall be capable of activation at any time;

2. Where two or more radiographic tubes are controlled by one exposure switch, the radiographic tube which has been selected shall be clearly indicated to the operator prior to initiation of the exposure. Certified units only shall be provided with such an indicator on both the x-ray control panel and at or near the radiographic tube housing assembly which has been selected; and

3. A radiographic tube shall be energized only when that specific radiographic tube is selected.

(i) No person shall operate or permit the operation of any certified radiographic x-ray equipment that has been provided with positive beam limitation (PBL) unless the following requirements for positive beam limitation are met:

1. When provided, positive beam limitation (PBL) shall function as described in 15.3(i)2 of this section whenever all the following conditions are met:

i. The image receptor is inserted into a permanently mounted cassette holder;

ii. The image receptor length and width are each less than 50 centimeters (20 inches);

iii. The x-ray beam axis is within plus or minus three degrees of vertical and the SID is 90 centimeters (35.5 inches) to 130 centimeters (51 inches) inclusive; or the x-ray beam axis is within plus or minus three degrees of horizontal and the SID is 90 centimeters (35.5 inches) to 205 centimeters (81 inches) inclusive;

iv. The x-ray beam is perpendicular to the plane of the image receptor to within plus or minus three degrees; and

v. Neither tomographic nor stereoscopic radiography is being performed.

2. When positive beam limitation (PBL) is provided it shall prevent the production of x-rays whenever:

i. Either the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimensions by more than three percent of the SID; or

ii. The sum of the differences, without regard to sign, between the length and width of the x-ray field in the plane of the image receptor and the corresponding dimensions of the image receptor exceeds four percent of the SID.

iii. The beam-limiting device is at an SID for which PBL is not designed for sizing.

3. Compliance with (i)2 above shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of (i)1 above are met. Determination of compliance shall be no sooner than five seconds after insertion of the image receptor.

4. If a capability for overriding PBL in case of system failure and for servicing the system is provided, it shall comply with the following:

i. This override shall be for all SID and image receptor sizes;

ii. A key shall be required to defeat the PBL;

iii. The key shall remain in place during the entire time the PBL system is overridden; and

iv. Each key switch or key shall be clearly and durably labeled as follows:

For X-ray Field Limitation System Failure

The override capability is considered accessible to the operator if it is referenced in the operator's manual or in other material intended for the operator if its location is such that the operator would consider it part of the operational controls.

5. When provided, the positive beam limitation system shall be capable of operation, at the discretion of the operator, in such a manner that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters (39.4 inches) shall be equal to or less than five centimeters by five centimeters (two inches by two inches); and

6. When provided, the positive beam limitation system shall be so designed that if a change in image receptor does not cause an automatic return to the positive beam limitation function as described in (i)2 above, then any change of image receptor size or SID must cause the automatic return.

(j) No person shall operate or permit the operation of certified or uncertified mobile or portable radiographic x-ray equipment unless the following requirements are met:

1. These requirements are in addition to and not in substitution for the applicable requirements of this subchapter;

2. The equipment shall be provided with a collimator and a spacer device to limit the source-to-skin distance to not less than 30 centimeters (12 inches);

3. If the equipment was manufactured with a device to measure the SID, the device shall be present to measure the SID and the device shall indicate the SID to within two percent;

4. The exposure control switch shall be of the dead-man type and shall be so arranged that the operator can stand at least six feet from the patient for all exposures. The exposure control switch when depressed shall not energize the x-ray tube when the timer is in the "off" or "0" position;

5. A mobile or portable radiographic unit used routinely in one location shall be considered a permanent installation and shall comply with the requirements of N.J.A.C. 7:28-15.10; and

6. No person shall operate or permit the operation of certified or uncertified mobile or portable equipment unless the person operating the equipment is protected with a lead apron of at least 0.25 mm lead equivalent.

(k) No person shall operate or permit the operation of certified or uncertified ionizing-radiation-producing podiatric x-ray equipment unless the following requirements are met:

1. These requirements are in addition to and not in substitution for the applicable requirements of this subchapter; and

2. Certified and uncertified podiatric x-ray equipment shall be provided with an exposure control switch which will allow the operator to stand at least six feet (1.8 meters) from the patient or behind a protective barrier. The requirement set forth in this paragraph shall supersede the requirement in (f)6 above.

7:28-15.4 Mammography radiographic installations

(a) This section establishes the requirements for medical diagnostic and screening radiographic mammography procedures. Hereafter, all references to mammography shall mean mammography performed with ionizing-radiation-producing equipment.

(b) The provisions of this section are in addition to and not in substitution for the applicable provisions of N.J.A.C. 7:28.

(c) No person shall operate or permit the operation of x-ray equipment used for mammography unless the equipment and installation meet the applicable requirements of this subchapter.

(d) The registrant shall ensure that each mammography unit under the registrant's jurisdiction is operated only by a licensed diagnostic x-ray technologist or a licensed practitioner as prescribed in N.J.A.C. 7:28-19.

(e) Within two years of the effective date of this rule or within two years of the installation of a mammography unit, whichever shall be later, the registrant shall not operate or permit the operation of each mammography unit under the registrant's jurisdiction unless the mammography unit is accredited by the American College of Radiology (ACR) or meets an equivalent standard acceptable to the Commission. Current accreditation by the ACR or its equivalent acceptable to the Commission shall be maintained for each mammography unit under the registrant's jurisdiction.

1. If a mammography unit is accredited or certified by an agency or organization other than ACR, a registrant may petition the Commission in writing for recognition of this agency's or organization's accreditation or certification as equivalent to ACR accreditation. The registrant shall submit sufficient documentation to the Commission related to machine performance standards, quality assurance, operating safety standards, and any additional information that the Commission may request in order to demonstrate equivalence to ACR

accreditation.

2. The Commission may approve the registrant's petition based on the information contained in the petition and the Commission's determination that the alternative agency's or organization's accreditation or certification is equivalent to ACR accreditation.

3. A mammography unit that is used exclusively for stereotactic biopsies is exempt from the requirements of 15.4(e) 1 and 2 above but shall meet the other requirements of this subchapter.

(f) No person shall operate or permit the operation of any radiographic equipment for mammography unless the equipment meets the following requirements:

1. It shall be a dedicated mammography unit;

2. The tube housing assembly shall be provided with a beam-limiting device. When a light localizer used to define the x-ray field is provided on the mammography unit, the light localizer shall provide an average illuminance of not less than 160 lux (15 footcandles) at 100 centimeters or at the maximum SID, whichever is less. The average illuminance shall be based upon measurements made in the approximate center of each quadrant of the light field.

3. The tube housing assembly shall be so constructed that the leakage radiation measured at a distance of one meter (39 inches) from the source does not exceed 26 microcoulombs per kilogram (0.1 Roentgen) in any one hour when the source is operated at its leakage technique factors;

4. A mark shall be provided on the visible exterior of the source assembly which indicates the location of the focal spot;

5. An x-ray beam-limiting device shall be used to restrict the size of the x-ray beam to the size of the image receptor. Types of beam-limiting devices include, but are not limited to, diaphragms, cones, and adjustable collimators. The beam-limiting device shall provide the same primary beam attenuation as the tube housing.

   i. The misalignment between the edges of the light field and the x-ray field shall be less than two percent of the SID.

   ii. The x-ray beam shall be totally intercepted by the image-receptor support, except for the edge of the image-receptor support designed to be adjacent to the chest wall. The x-ray field at the edge of the image-receptor support designed to be adjacent to the chest wall shall not extend beyond the edge of the image-receptor support by more than two percent of the SID;

6. The image-receptor support shall transmit less than 0.026 microcoulombs (0.1 milliroentgens) per exposure at 5 centimeters (2 inches) beyond the support with no breast present for maximum kV and mAs values clinically used;

7. The requirements for the control panel on the mammography system are as follows:

   i. The mammography system shall have the capability of automatic exposure control;

   ii. The control panel shall provide visual display of the x-ray tube voltage (kVp) and either the tube current (mA) and time setting (sec) or the product of the tube current and time

setting in millampere-seconds (mAs); and iii. The control panel shall have a device or means for emitting a signal audible to the operator which indicates when the exposure has terminated and a device such as a light or milliammeter to give a visual indication when the beam is on;

8. The radiation exposure reproducibility shall not exceed a coefficient of variation of 0.05. For manual mode this shall be for any selected technique factors. For automatic exposure control this shall be for any selected absorber or phantom;

9. The timer shall meet the following requirements:

   i. The timer reproducibility shall not exceed a coefficient of variation of 0.05 for any specific combination of selected technique factors; and

   ii. The timer accuracy shall not exceed the limits specified by the manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10 percent of the indicated value;

10. The kVp shall meet the following requirements:

   i. The kVp accuracy shall not exceed the limits specified by the manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed ñ five percent from the nominal kVp setting;

   ii. The kVp reproducibility shall not exceed a coefficient of variation of 0.02;

   iii. The kVp shall be capable of being selected in increments of no greater than three kVp whether kVp is selected manually or automatically; and

   iv. The kVp shall be selected either manually or automatically;

11. The following linearity requirements apply to mammography x-ray equipment which allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rating:

   i. For x-ray equipment having independent selection of x-ray tube current (mA), the average ratios of exposure to the indicated milliampere-seconds product (mR/mAs) or (C/kg/mAs) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum.

   ii. For equipment manufactured after May 3, 1994, x-ray equipment having a combined x-ray tube current-exposure time product (mAs) selector, the average ratios of exposure to the indicated milliampere-seconds product (mR/mAs) or (C/kg/mAs) values obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum.

   iii. The average exposure ratio for (f) 11i and 11ii above shall be expressed as follows:

$$|X1 - X2| \text{ ó } 0.10\ (X1 + X2)$$

where X1 and X2 are the average mR/mAs or C/kg/mAs values obtained at each of two consecutive tube mA or mAs settings.

12. The measured HVL shall be equal to or greater than the value:

    kVp
    HVL ò (in units of mm of aluminum)
    100

    For film-screen mammography units only, the maximum measured HVL shall be equal to or less than the value:

    kVp
    HVL ó + 0.1 (mm of aluminum)
    100

13. There shall be a device to maintain parallel breast compression. The degree of compression shall be adjustable and shall remain at the set level during the exposure. A device, scale or other means shall indicate the thickness of the compressed breast. The compression plate shall attenuate the beam by no more than the attenuation provided by two mm of polymethylacrylate;

14. There shall be a means or a device on the mammography unit to indicate the SID, if this is variable. The actual SID shall be posted on the mammography unit if this distance is fixed. Accuracy of the SID indicator shall be within ñ two percent of the indicated value;

15. There shall be a means of determining the angulation on the mammography unit. This determination shall be displayed on the unit.

    i. There shall be a means to lock the position and angulation of the source assembly.

    ii. Such lock shall be deemed to have been provided if the position or angulation can only be changed by activation of a motor; and

16. The exposure switch shall be a dead-man type and shall be arranged so that it can only be operated when the operator is within a shielded area. The exposure control when depressed shall not energize the x-ray tube when the timer is in the "off" or "zero" position.

(g) A radiation-protection barrier for the operator shall be provided in the room for a mammography unit that requires the operator to remain in the room during the exposure. The operator shall stand behind the protective barrier provided and shall observe the patient during each mammographic exposure.

(h) No person shall operate or permit the operation of a mammography unit unless the registrant has developed and maintains a quality assurance program that meets the requirements listed in (j) below.

(i) The registrant shall ensure that no person operates the mammography unit until he or she has reviewed the quality assurance manual and has documented that such review has been completed.

(j) The requirements for the quality assurance program shall be as follows:

1. The registrant shall develop and maintain a quality assurance manual that identifies and assigns over-all quality control responsibilities. The following items shall be in the quality assurance manual:

i. A list of the individuals responsible for testing, supervising, repairing or servicing the equipment. This list shall include the specific responsibilities for the radiologist, the qualified medical physicist for the supervision of quality assurance programs for diagnostic x-ray equipment (the medical physicist), the diagnostic x-ray technologist (radiologic technologist), and repair or service personnel;

ii. A list of the equipment to be tested;

iii. A list of the tests to be performed. For each test, the following items shall be included:

(1) The frequency of performance of each test in accordance with (j)4, 6, 7, 8, 9, 10, and 11 below;

(2) The acceptability limits for each test; and

(3) A brief description of the procedures to be used for each test;

iv. The protocol for corrective action which shall be taken if the test results do not lie within the acceptability limits.

v. Sample forms to be used for each test; and

vi. Reference materials and their location;

2. The registrant shall present the quality assurance manual, records of all testing, test data, equipment maintenance and other required procedures to the department for review during any inspection;

3. For each mammography unit, the registrant shall ensure that tests are performed and records are maintained as listed below:

i. The initial test results shall be maintained for as long as the mammography unit is registered plus one year; and

ii. A record of each service to the mammography unit shall be kept for 36 months from the date of such service;

4. For each mammography unit, the registrant shall perform or have performed at least annually the test procedures listed below and shall maintain the records for as long as the mammography unit remains registered plus one year.

i. Measurement of breast entrance exposure and average glandular dose;

ii. Measurement of half-value layer;

iii. Measurement of accuracy and reproducibility of kVp settings;

iv. Measurement of linearity of exposure at various mA stations or mAs settings;

v. Measurement of accuracy and reproducibility of timer settings where these are adjustable;

vi. Measurement of exposure reproducibility at techniques representative of clinical use;

vii. Measurement of focal spot size;

viii. Assessment of performance of automatic exposure control system, including short-term reproducibility, kilovoltage and thickness compensation, density control selector function and back-up timer function;

ix. Assessment of mammography unit assembly, including accuracy of source-to-film distance indicator, physical integrity of breast thickness indicator, functioning of all locks, detents, angulation indicators and mechanical support for the x-ray tube and image-receptor-holder assembly; and x. Assessment of collimation, including alignment of light field and x-ray field;

5. For each processor used for mammography, the registrant shall ensure that the records of maintenance and quality control tests are maintained in a processor maintenance log. Processor maintenance logs shall include preventive maintenance, cleaning performed and corrective actions taken. A record of each such measure taken shall be maintained in the log for at least 36 months;

6. For each processor used for film-screen mammography, the registrant shall perform or have performed quality control tests for each processor on each day the processor is used for mammography. For motor vehicle and mobile mammographic units with processing capability, quality control tests for each processor shall be performed at each new location.

   i. Quality control tests shall include measurement of developer temperature, film sensitometry to indicate film speed, film contrast and base-plus-fog density.

   ii. Logs, charts, or graphs of these measurements shall be maintained for 36 months from the dates of such measurements. The registrant may discard such records after 36 months, except that at least one representative set of quality control records from each year shall be maintained for an additional five years;

7. For each darkroom used for loading, storing or processing film used for mammography, the registrant shall ensure that:

   i. Measurement of film fog is performed at least semiannually and test results are maintained for the current year and the preceding year; and

   ii. Darkroom cleanliness is maintained and checked daily;

8. For each radiographic cassette used for film-screen mammography, the registrant shall ensure that:

   i. The intensifying screen is cleaned and inspected at least weekly;

   ii. The film-screen contact is tested at least semiannually and the record of each test is maintained for at least 36 months from the date of the test; and

   iii. Uniformity of screen speed is assessed annually and the record of each test is maintained for at least 36 months from the date of the test;

9. For each component used for xeromammography, the registrant shall perform or have performed the quality control tests listed below:

   i. For the conditioner, tests for light leaks, temperature of relaxation oven, charging of the

plate, and optimization for the kVp used shall be performed on each day the conditioner is used for mammography.

ii. For the processor, tests for light leaks, toner supply, back bias setting, and optimization for the kVp used shall be performed on each day the processor is used for mammography;

iii. Each cassette shall be cleaned and checked for dust particles and pressure artifacts every week; and

iv. Each selenium plate shall be examined for powder deficiency spots, powder efficiency spots, dark dusting, scratches, and artifacts on a monthly basis;

10. For each mammography unit, the registrant shall ensure that the following image quality assessments are performed:

i. A phantom is used whose image can be quantitatively scored;

ii. For fixed units, mammographic phantom image quality is tested monthly;

iii. For mobile units and motor vehicle mounted units, mammographic phantom image quality is tested after each relocation and at least monthly. Equipment must be recalibrated prior to use to maintain quality of the phantom image; and

iv. At least one test phantom image for each mammography unit is maintained for each month of the current calendar year and for the preceding year. The registrant shall also maintain at least one phantom image a year for each mammography unit beginning from the year of installation;

11. Repeat analysis shall be performed at least quarterly for film-screen mammography and xeromammography; and

12. Technique charts or standard settings of factors such as density, kVp, focal spot selection, listing of all factors appropriate to the design of the mammography unit shall be posted either next to or on each mammography unit.

7:28-15.5 Medical fluoroscopic x-ray systems

(a) The provisions of this section are in addition to and not in substitution for the applicable provisions of N.J.A.C. 7:28.

(b) No person shall operate or permit the operation of certified or uncertified fluoroscopic x-ray equipment used in the healing arts unless the equipment meets the following requirements:

1. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any source-to-image receptor distance.

i. The x-ray tube used for fluoroscopy shall not produce x-rays unless the primary protective barrier is in position to intercept the entire useful beam. Radiation therapy simulator systems shall be exempt from this requirement provided the systems are intended only for remote control operation and the manufacturer sets forth instructions for assemblers with respect to control location as part of the information required to be

in the manufacturer's specifications manual and provides the registrant with precautions concerning the importance of remote control operation.

ii. The exposure rate due to transmission through the primary protective barrier with an attenuation block in the useful beam combined with the radiation from the image intensifier, if provided, shall not exceed 5.2 E-6 Coulombs per kilogram (two milliroentgens per hour) at 10 centimeters (four inches) from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each Roentgen per minute of entrance exposure rate. The attenuation block shall be a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters (eight inches by eight inches by 1.5 inches), of type 1100 aluminum alloy or aluminum alloy having equivalent attenuation. Radiation therapy simulator systems shall be exempt from this requirement provided the systems are intended only for remote control operation and the manufacturer sets forth instructions for assemblers with respect to control location as part of the information required to be in the manufacturer's specifications manual and provides the registrant with precautions concerning the importance of remote control operation.

iii. The exposure rate due to transmission through the primary barrier combined with radiation from the image intensifier, if provided, shall be determined by measurements averaged over an area of 100 square centimeters (15.5 square inches) with no linear dimension greater than 20 centimeters (eight inches). If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters (12 inches) above the tabletop. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters (12 inches). Movable grids and compression devices shall be removed from the useful beam during the measurement. For all measurements, the attenuation block shall be positioned in the useful beam 10 centimeters (four inches) from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly. For C-arm fluoroscopy equipment, the measurement shall be made with the end of the beam-limiting device at the minimum SID and the attenuation block not closer than 30 centimeters (12 inches) from the imaging assembly.

iv. For uncertified fluoroscopic equipment only, the fluoroscopic screen shall be covered with a transparent protective material such that under normal operating conditions the dose rate measured five centimeters from the viewer's side of the screen shall not be more than 20 milliroentgens per hour (5.2 E-6 Coulombs per kilogram) without a patient and with the screen 20 centimeters (eight inches) from the tabletop or panel;

2. For fluoroscopic equipment that does not have image intensification the following field limitation requirements shall be met:

i. The x-ray field shall not extend beyond the visible area of the image receptor;

ii. Means shall be provided for stepless adjustment of the field size;

iii. The minimum field size at the greatest SID shall be equal to or less than five centimeters by five centimeters (two inches by two inches); and

iv. Equipment manufactured after February 25, 1978, which permits a variable angle between the image receptor and the axis of the x-ray beam shall be provided with a means to indicate when the axis of the x-ray beam is perpendicular to the plane of the

image receptor;

3. Except for fluoroscopic systems used for radiation therapy simulation, image-intensified fluoroscopic equipment shall meet the following field limitation requirements:

   i. Neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent of the SID;

   ii. The sum of the excess length and the excess width shall be no greater than four percent of the SID.
   Compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor;

   iii. For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined by comparison of the length and width of the x-ray field with the diameter of the visible area of the image receptor which parallels each;

   iv. Equipment manufactured after February 25, 1978, in which the angle between the image receptor and beam axis is variable, shall be provided with a means to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor;

   v. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters (46.5 square inches) shall be provided with a means for stepless adjustment of the x-ray field;

   vi. Equipment with a fixed SID and a visible area of 300 square centimeters (46.5 square inches) or less shall be provided with either stepless adjustment of the x-ray field or with some other means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters (19.4 square inches) or less;

   vii. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of five centimeters by five centimeters (two inches by two inches) or less; and

   viii. Fluoroscopic x-ray equipment that automatically adjusts the field size as the SID is changed may be provided with a capability for overriding the automatic adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic field adjustment is overridden. Each such system failure override switch shall be clearly labeled "FOR X-RAY FIELD LIMITATION SYSTEM FAILURE";

4. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the operator for the entire time of any exposure. When recording serial fluoroscopic images, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in progress;

5. Fluoroscopic equipment which is provided with automatic exposure rate control or with both automatic exposure rate control and manual mode (dual mode units) shall not be operable at any combination of tube potential and current which will result in an entrance exposure rate in excess of 10 Roentgens per minute (2.6 E-3 Coulombs per kilogram per minute) at the point where the center of the useful beam enters the patient except:

i. During the recording of fluoroscopic images; or

ii. When an optional high-level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an entrance exposure rate in excess of 5 Roentgens (1.3 E-4 Coulombs/kilogram/minute) at the point where the center of the useful beam enters the patient unless the high-level control is activated;

6. Fluoroscopic equipment which is not provided with automatic exposure rate control (manual mode) shall not be operable at any combination of tube potential and current which will result in an entrance exposure rate in excess of five Roentgens per minute (1.3 E-4 Coulombs/kilogram/minute) at the point where the center of the useful beam enters the patient, except:

   i. During recording of fluoroscopic images; or

   ii. When an optional high-level control is activated;

7. For equipment provided with high-level control, the following requirements shall be met:

   i. Special means of activation of high-level controls shall be required (for example, two-step foot pedal);

   ii. Continuous manual activation of the high-level control shall be provided by the operator; and

   iii. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed;

8. Measuring compliance of entrance exposure rates shall be determined as follows:

   i. When the source is below the table, the entrance exposure rate shall be measured one centimeter (0.4 inch) above the tabletop or cradle.

   ii. When the source is above the table, the entrance exposure rate shall be measured at 30 centimeters (12 inches) above the tabletop with the end of the beam-limiting device or spacer positioned as close as possible to the point of measurement.

   iii. For stationary and mobile c-arm types of fluoroscopes, the entrance exposure rate shall be measured 30 centimeters (12 inches) from the input surface of the fluoroscopic imaging assembly.

   iv. In a lateral type of fluoroscope, the entrance exposure rate shall be measured 15 centimeters (5.9 inches) from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters (5.9 inches) to the centerline of the x-ray table;

9. Fluoroscopic radiation therapy simulation systems are exempt from the entrance exposure rate requirements of (b)5 and (b)6 above;

10. The x-ray tube potential and current shall be continuously indicated to the operator and/or at the control panel during fluoroscopy and cinefluorography. Deviation of x-ray tube potential

and current from the indicated values shall not exceed the maximum deviation as stated by the manufacturer;

11. A means shall be provided to limit the source-to-skin distance to not less than 38 centimeters (15 inches) on stationary fluoroscopes and to not less than 30 centimeters (12 inches) on mobile and portable fluoroscopes.

    i. Image-intensified fluoroscopes intended for specific surgical applications that would be impossible to perform at the source-to-skin distances specified above, may be operated at shorter source-to-skin distances but in no case less than 20 centimeters (eight inches);

12. The following requirements shall apply to a fluoroscopic timer:

    i. A means shall be provided to preset the cumulative on-time of the fluoroscopic tube. The maximum cumulative time of the timer shall not exceed five minutes without resetting;

    ii. The timer shall either terminate the exposure or emit a signal audible to the fluoroscopist when the exposure time reaches five minutes. Such signal shall continue to sound while x-rays are produced until the timer is reset; and

    iii. As an alternative to the requirements of (b)12ii above, radiation therapy simulation systems may be provided with a means to indicate the total cumulative exposure time during which x-rays were produced, and which is capable of being reset between x-ray examinations;

13. Mobile and portable fluoroscopes shall be provided with image intensification;

14. The fluoroscopy table that is provided with an undertable tube and a bucky shall have a bucky slot cover that provides protection equivalent to at least 0.5 millimeters of lead. Radiation therapy simulation systems are exempt from the requirements of this paragraph.

15. Protective shielding, such as a drape, shall be in place between the patient and fluoroscopist and shall provide protection equivalent to at least 0.5 millimeters of lead;

16. When a sterile field will not permit the use of the normal protective barriers, the requirements of (b)15 above may be omitted.

17. A mobile fluoroscopic unit used routinely in one location shall be considered a permanent installation and shall comply with the shielding and survey requirements in N.J.A.C. 7:28-15.10; and

18. The following requirements shall apply to spot-film devices except when the spot-film device is provided for use with a radiation therapy simulator system:

    i. A means shall be provided between the source and the patient which will automatically limit the x-ray field at the time the exposure is initiated to no more than that portion of the image receptor chosen by the operator on the spot-film selector. If the x-ray field size is less than the size of the selected portion of the image receptor, the field size shall not open automatically to the size of the selected portion of the image receptor unless the operator has selected such a mode of operation;

    ii. Neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image

receptor by more than three percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum of the differences in length and width, without regard to the sign, shall not exceed four percent of the SID. Spot-film devices manufactured after February 25, 1978, which permit a variable angle between the plane of the image receptor and beam axis, shall be provided with a means to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor;

iii. The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within two percent of the SID;

iv. Means shall be provided to reduce the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor such that:

(1) For spot-film devices used on fixed-SID fluoroscopic systems which are not required to provide, and do not provide stepless adjustment of the x-ray field, the minimum field size, at the greatest SID, shall not exceed five by five centimeters (two by two inches); or

(2) For spot-film devices used on fluoroscopic systems that have a variable SID and/or stepless adjustment of the field size, each dimension of the minimum field size, and the greatest SID, shall not exceed five centimeters (two inches); and

v. A capability may be provided for overriding the automatic x-ray field size adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic x-ray field size adjustment override is engaged. Each such system failure override switch shall be clearly labeled as follows: FOR X-RAY FIELD LIMITATION SYSTEM FAILURE.

7:28-15.6 Radiation therapy simulators

(a) No person shall operate or permit the operation of a radiation therapy simulator system unless it meets the requirements of this section and complies with all applicable requirements of this subchapter, unless otherwise exempted.

(b) Operation of a radiation therapy simulator system on a patient shall be performed only by a licensed practitioner, a licensed radiation therapy technologist, or a licensed diagnostic x-ray technologist, as prescribed in N.J.A.C. 7:28-19.

(c) No person shall operate or permit the operation of a radiation therapy simulator system unless it meets the following requirements:

1. A quality assurance program has been established in collaboration with a qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems, and implemented by the registrant to ensure congruence of the position and size of the simulated field with the position and size of the irradiation field.

i. The quality assurance program is consistent with, but not limited to, the guidelines established by the American Association of Physicists in Medicine, (AAPM) Report Number 13;

ii. The quality assurance program is documented by the registrant; and

iii. The quality assurance program records are maintained by the registrant for at least 36 months, and are available for review at the facility by the department during any

inspection;

2. Any radiation therapy simulator system, which uses a gantry rotation system when performing radiographic examinations, shall be equipped with a sensor mechanism that shall stop the gantry motion if necessary to prevent collision. This requirement shall take effect one year after the effective date of this subchapter.

   i. Restarting the unit shall only be possible when the cause of the termination has been determined and corrected and the sensor mechanism is satisfied that a collision reoccurrence is not possible.

   ii. Tests of the operation of the anti-collision sensor mechanism are performed and results are documented by those individuals listed in (b) above or by a qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems at intervals not to exceed 12 months. The records shall be maintained for at least 36 months, and shall be available at the facility for review by the department during any inspection. A true copy of these records shall be sent to the department upon request;

3. A dead-man switch and/or an emergency "off" control shall be located on the remote control console and also at all places in the simulator room from which motions are controlled;

4. A radiation therapy simulator system attached to a megavoltage radiation therapy x-ray system shall meet the following requirements:

   i. Exposure controls shall be located outside the therapy room;

   ii. The operator shall be able to view the patient from the control panel at all times during the procedure. The viewing system may consist of, but is not limited to, a window, mirror, or closed circuit television; and

   iii. A method for two-way aural communication between the patient and the operator shall be provided at the control panel and shall be operable at all times when the system is in operation;

5. A superficial or orthovoltage therapy x-ray system shall not be used for radiation therapy simulation except for treatments given on this system; and

6. Protective aprons of at least 0.25 millimeters lead equivalent shall be worn by the operator or therapy physician during every instance in which entry into the simulator room is necessary while the patient exposure is in progress. Protective gloves of at least 0.25 millimeters lead equivalent shall be worn by the operator or therapy physician during every instance when the hands must be in the primary beam while the patient exposure is in progress. The exposure of such individuals shall be controlled by the use of shielding and protective clothing as necessary to ensure that they are not exposed to radiation doses in excess of those permitted by N.J.A.C. 7:28-6.

7:28-15.7 Computed tomography equipment

(a) The provisions of this section are in addition to and not in substitution for the applicable sections of this subchapter.

(b) No person shall operate or permit the operation of computed tomography equipment used in the healing arts unless the equipment meets the following requirements:

1. The registrant shall maintain the technical and safety information supplied by the manufacturer as required by the Code of Federal Regulations at 21 C.F.R. 1020.33(c) near the control panel and produce it to the department during any inspection;

2. The registrant shall ensure that a CT quality assurance phantom is available for testing the CT system. The use of the phantom and the physical properties of the phantom shall meet the following requirements:

    i. Instructions on the use of the phantom shall be provided. The instructions shall include a schedule of tests appropriate for the CT system, the allowable variations for the test parameters, and a method to store the test results;

    ii. Images of the phantom that demonstrate compliance with the CT's performance specifications shall be obtained on both film and digital archive media. These images shall be maintained and used to compare with current test results; and

    iii. The phantom shall be capable of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measurement of the mean CT number of water or a reference material;

3. The registrant shall ensure that a CT dosimetry phantom is available for testing the CT system. The use of the phantom and the physical properties of the phantom shall meet the following requirements:

    i. The phantom shall be a right circular cylinder of polymethyl-methacrylate of density 1.19 ñ0.01 grams per cubic centimeter;

    ii. The phantom shall be at least 14 centimeters in length and shall have a diameter of 32.0 centimeters for testing any CT system designed to image any section of the body (whole body scanners);

    iii. The phantom shall be at least 16.0 centimeters in diameter for any system designed to image the head (head scanner) or for any whole body scanner operated in the head scanning mode;

    iv. The phantom shall provide means for the placement of a dosimeter(s) along its axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom; and

    v. Any effect on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom;

4. A visual indication of the conditions of operation to be used during a scan or scan sequence shall be indicated prior to initiation of a scan or scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions shall be visible from any position from which the scan can be initiated;

5. A means shall be provided to terminate the exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data

collection. A visible signal shall indicate when the x-ray exposure has been terminated by this means. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of the preset value through the use of either a backup timer or devices which monitor equipment function. Means shall be provided such that the exposure from the system does not exceed 100 mR/scan except when x-ray transmission data are being collected for use in image production or technique factor selection;

6. The operator shall be able to terminate the x-ray exposure at any time during a scan or during a series of scans under the x-ray system control of greater than one-half second exposure. Termination of the x-ray exposure shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan;

7. A means shall be provided to permit visual determination of the location of the tomographic plane or a reference plane offset from the tomographic plane;

8. If a device using a light source, including a laser source, is used to determine the location of the tomographic plane, this source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux;

9. The x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed. If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for one-half second. Indicators at or near the housing of the scanning mechanism shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible;

10. For systems that allow high voltage to be applied to the x-ray tube continuously and that control the emission of x-rays with a shutter, the radiation emitted shall not exceed 100 milliroentgens (2.6 E-2 Coulombs per kilogram) in one hour at any point five centimeters (two inches) outside the external surface of the housing of the scanning mechanism when the shutter is closed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters (15.5 square inches) with no linear dimensions greater than 20 centimeters (eight inches);

11. The deviation of indicated scan increment from actual scan increment shall not exceed 1 millimeter. Compliance shall be measured as follows: The determination of the deviation of indicated versus actual scan increment shall be based on measurements taken with a mass of 100 kilograms or less on the patient support. The patient support shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters (12 inches), whichever is less, and then returned to the starting position;

12. The distance between the indicated location of the tomographic plane or reference plane and its actual location may not exceed five millimeters; and

13. An emergency off switch shall be available at the control panel and in the CT room.

(c) No person shall operate or permit the operation of computed tomographic equipment unless the facility meets the following:

1. Provision shall be made for two-way aural communication between the patient and the operator at the control panel; and

2. Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit

continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel. When the primary viewing system is by electronic means, such as a closed-circuit television, an alternate viewing system, which may also be electronic, shall be provided to permit continuous observation of the patient during irradiation in the event of failure of the primary viewing system.

(d) No person shall operate or permit the operation of computed tomography x-ray equipment used in the healing arts unless the following operating conditions are met:

1. The CT system shall not be operated except by a licensed individual who has been specifically trained in its operation;

2. Information shall be available near the control panel regarding the operation and calibration of the system. That information shall contain:

i. Dates of the latest calibration and spot checks and the location within the facility where the results of these tests may be obtained;

ii. Instructions on the use of the phantom(s), including a schedule of testing appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent tests conducted on the system; and

iii. A technique chart shall be available at the control panel; and

3. The registrant shall ensure that a qualified medical physicist for the supervision of quality assurance programs for diagnostic x-ray equipment does performance testing procedures annually, which shall include but not be limited to CTDI, nominal tomographic section thickness accuracy, incremental table movement accuracy, noise, and high contrast and low contrast resolution.

7:28-15.8 Medical cabinet x-ray systems

(a) The requirements of this section are in addition to and not in substitution for the applicable requirements in N.J.A.C. 7:28.

(b) No person shall operate or permit the operation of a medical cabinet x-ray system used in the healing arts unless it meets the following requirements:

1. The registrant shall ensure and document that the operator has received a copy of the operator's manual, has been trained in the operating procedures for the system, and has demonstrated competence in operating the system to the registrant. This documentation shall be available to the department for review during any inspection. The registrant shall maintain a copy of the operator's manual in the proximity of the system;

2. Radiation emitted from the medical cabinet x-ray system shall not exceed an exposure of 0.5 milliroentgens in one hour at any point five centimeters outside the external surface;

3. No medical cabinet x-ray system shall be placed into operation until the registrant demonstrates that a qualified individual for the performance of radiation surveys for diagnostic x-ray equipment has determined that the exposure level in (b)2 above is not exceeded. Where an operating system is subsequently modified, repaired, or moved to a new location, the unit shall not be used until a qualified individual for the performance of radiation surveys for diagnostic x-ray equipment has determined compliance with this limit. The registrant shall maintain the original report(s) at the facility, and make the report(s)

available to the Department during any inspection. The registrant shall submit a copy of the report(s) to the department within 30 days of the date the determination has been completed.

4. Safety interlocks shall be provided on medical cabinet x-ray systems as follows:

   i. Each door of a cabinet x-ray system shall have a minimum of two safety interlocks installed in such a manner that the opening of any door would disconnect the energy supply circuit to the high-voltage generator;

   ii. Each access panel on a cabinet x-ray system shall have at least one safety interlock;

   iii. Following interruption of the energy supply circuit by the functioning of any safety interlock, a manually reset control switch shall be activated before x-ray production can resume;

   iv. Failure of any single component of the medical cabinet x-ray system shall not cause failure of more than one required safety interlock; and

   v. Safety interlocks shall be tested for operation at intervals not to exceed six months. A record of these tests shall be maintained for review by the department during any inspection;

5. A medical cabinet x-ray system shall have a permanent floor, which means the underside external surface of the cabinet;

6. There shall be permanently affixed or inscribed on the medical cabinet x-ray system at the location of any controls which can be used to initiate x-ray production a clearly legible and visible label bearing the statement or words having a similar meaning: "CAUTION: X-RAYS PRODUCED WHEN ENERGIZED"; and

7. All medical cabinet systems shall be provided with the following controls and indicators:

   i. A key-activated control to insure that x-ray production is not possible with the key removed;

   ii. A control button or control switch to initiate and terminate the production of x-rays other than by the functioning of a safety interlock or the main power control;

   iii. A warning light at the control button or control switch that indicates when and only when x-rays are being produced. This light shall be clearly labeled with the words: "X-RAY ON";

   iv. A warning light which indicates when and only when x-rays are being produced. This warning light shall be visible from each door, access panel, and port, and shall be clearly labeled with the words: "X-RAY ON"; and

   v. A means to indicate the kilovoltage, current and time during the production of x-rays at each x-ray control button or control switch unless the x-ray tube current is preset.

7:28-15.9 Individual radiation safety

(a) No person shall operate or permit the operation of certified or uncertified medical radiographic and fluoroscopic equipment or therapy simulation systems unless the following conditions are met:

1. Only individuals required for the medical procedure, for training, or for equipment maintenance shall be in the radiographic or fluoroscopic or therapy simulator room during an exposure.

    i. Individuals who are present in a radiographic or fluoroscopic or therapy simulator room during any exposure shall wear protective aprons of at least 0.25 mm lead equivalent during every exposure.

    ii. Protective gloves of at least 0.25 mm lead equivalent shall be worn by the fluoroscopist and assistant(s) during every examination when it is required that their hands be placed in the useful beam;

2. When a patient must be provided with auxiliary support during a radiation exposure and mechanical holding devices are insufficient, the following procedures shall be followed:

    i. The person holding the patient shall be protected with a lead apron of at least 0.25 mm lead equivalent;

    ii. The person holding the patient shall be protected with lead gloves of at least 0.25 mm lead equivalent if the hands must be placed in the useful beam;

    iii. No licensed practitioner shall order or otherwise cause an individual who is licensed pursuant to N.J.S.A. 26:2D and this chapter to hold a patient during a radiation exposure, except in a life-threatening situation;

    iv. No person shall be employed, routinely assigned, or required to hold a patient during radiographic and fluoroscopic procedures;

    v. If a patient must be held during the x-ray exposure, non-radiation workers such as aides, orderlies, nurses, or members of the patient's family may be asked to perform this duty; and

    vi. No person other than the patient shall hold the film during the exposure;

3. Gonadal shielding of not less than 0.5 mm lead equivalent shall be used on a patient during radiographic and fluoroscopic procedures, except for cases in which this would interfere with the diagnostic procedure. If the patient is sterile, the use of gonadal shielding may be omitted;

4. The operator shall collimate x-ray units that do not have positive beam limitation to ensure that the x-ray field does not extend beyond the image receptor;

5. The radiographic field shall be restricted to the area of clinical interest as far as practical;

6. A method to observe the patient during the x-ray exposure shall be provided for all units. Observation of the patient shall be made from the shielded area;

7. During radiographic exposures, the operator shall stand behind the protective barrier;

8. The registrant shall provide written safety rules to each individual operating x-ray equipment including any restrictions as to the operating technique required for the safe operation of the particular x-ray apparatus, and require that the operator sign a form acknowledging that the

safety manual was read. These safety rules and restrictions shall be made available for review by the Department during any inspection;

9. No person shall permit or arrange for the intentional irradiation of a human being except for the purpose of medical diagnosis or treatment;

10. No person shall deliberately expose an individual to the useful beam for the sole purpose of training or demonstration; and

11. No person shall operate an ionizing-radiation-producing machine unless that person understands and uses the principles of radiation safety to keep radiation exposure as low as reasonably achievable.

7:28-15.10 Structural shielding and radiation safety surveys

(a) No person shall operate or permit the operation of x-ray equipment used in the healing arts unless permanent structural shielding and/or protective barriers are used as necessary to ensure that no person other than the patient being examined receives a dose in excess of the limits specified in N.J.A.C. 7:28-6.

(b) No person shall operate or permit the operation of x-ray equipment used in the healing arts unless the survey requirements listed below are met. To the extent that this section imposes more stringent requirements than the survey requirements in N.J.A.C. 7:28-7 and recordkeeping requirements in N.J.A.C. 7:28-8, the requirements of this section shall be followed.

1. The registrant of a medical ionizing-radiation-producing machine shall ensure that a qualified individual for the performance of radiation surveys for diagnostic x-ray equipment and therapy simulators performs or supervises the performance of a radiation safety survey of the environs and submits a copy of the radiation safety survey report to the Department within 60 days of the date the machine is acquired. The registrant shall maintain the original survey report for as long as the machine is registered plus one year and shall make the original survey report available to the Department during any inspection.

2. The registrant of a medical ionizing-radiation-producing machine shall ensure that a qualified individual for the performance of surveys for diagnostic x-ray equipment and therapy simulator systems performs or supervises the performance of a radiation safety survey of the environs when changes have been made to shielding, equipment, or equipment location which affect the radiation levels of the environs. A copy of the survey report shall be submitted to the Department within 60 days of the date of such change. The registrant shall maintain the original survey report for as long as the machine is registered plus one year and shall make the original survey report available to the Department during any inspection.

3. The minimum requirements for the information to be included in the radiation safety survey report are as follows:

i. The name of the registrant of the installation as listed on form VRH-001, address, telephone number, and room location of the unit;

ii. The New Jersey Registration Number, if available;

iii. The manufacturer, model number, generator serial number, control panel serial number, tube manufacturer, tube serial number, and tube housing number;

iv. The name and address of the qualified individual performing the survey;

v. The date of survey;

vi. The survey instrument manufacturer, model number, and date calibrated;

vii. A diagram or floor plan of the area indicating the x-ray tube location, exposure switch location, normal operator position, lead shielding if present, wall, floor, and ceiling construction, labeling all areas adjacent to the exposure room including those above and below, and labeling of all areas as to occupancy and use;

viii. Records of the measurement of radiation exposure with a suitable phantom in the average patient position.

Measurements shall be taken at the operator's position and at all nearby locations which are normally occupied. For each measurement, the kVp, mA, exposure time, instrument reading, and correction made to the instrument reading (such as energy response, calibration, etc.) shall be recorded; and

ix. Exposure rates at each measured location shall be converted into Coulombs/kilogram/week or mR/week. Records shall include all assumptions of workload, use and occupancy factors used in the calculations.

7:28-15.11 Prohibited installations

(a) No person shall operate, permit to be operated, maintain or display in working condition any of the following:

1. Shoe-fitting fluoroscopic devices.

2. Chest photofluorographic machine after one year from the effective date of these rules.

3. Fixed vertical systems designed for non-image intensified fluoroscopy used for radiography after one year from the effective date of these rules.

4. Uncertified fluoroscopic equipment that does not have image intensification after one year from the effective date of these rules; or

5. Hand-held fluoroscopic screens.

7:28-15.12 Severability

If any provision of this subchapter or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of the subchapter, which can be given effect without the invalid provision or application, and to this end, the provisions of this subchapter are declared to be severable.

SUBCHAPTER 16: DENTAL RADIOGRAPHIC INSTALLATIONS16: DENTAL RADIOGRAPHIC INSTALLATIONS

7:28-16.1 Scope

(a) This subchapter establishes the requirements for dental radiographic installations.

(b) No person shall operate or permit the operation of x-ray equipment used in the practice of dentistry unless the equipment and installation meet the applicable requirements of this subchapter.

(c) The provisions of this subchapter are in addition to and not in substitution for the applicable provisions of N.J.A.C. 7:28- 1 through 3,5, through 8, 13 and 19.

7:28-16.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

"Certified components" means components of x-ray systems which are subject to the regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968, 21 Code of Federal Regulations, Chapter 1, Subchapter J-Radiological Health.

"Certified unit" means an x-ray system which has only certified components.

"Coefficient of variation" or "C" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

c = s over overline x = 1 over overline x {left[sum from{i = 1} to n {(x sub i - overline x)} sup 2 over {n - 1}right]} sup {1/2}
where s = Estimated standard deviation of the population.
X = Mean value of observations in sample.
X = ith observation sampled.
n = Number of observations sampled

"Control panel" means the x-ray system component and operational controls that include the indicators for x-ray tube voltage (kVp), tube current (mA), timer setting and beam on.

"Diagnostic type protective tube housing " means an x-ray tube housing so constructed that the leakage radiation measured at a distance of one meter (39.37 inches) from the source does not exceed 100 milliroentgens in one hour when the tube is operated at its maximum continuous rated current for the maximum continuous rated tube potential.

"Kilovolts peak" (see "peak tube potential").

"kV" means kilovolts.

"kVp" (see "peak tube potential").

"Image receptor" means any device such as, but not limited to, a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations. In those cases where a device is provided to preselect portions of the image receptor, the term "image receptor" shall mean the preselected portion of the device.

"Leakage radiation" means all radiation emanating from the diagnostic source assembly except the useful beam. Leakage radiation also means radiation produced when the exposure switch or timer is not activated.

"mA" means milliampere.

"mAs" means milliampere second.

"Multiple dental radiographic tube installation" means an installation in which one control panel may energize more than one x-ray tube.

"Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

"Primary protective barrier" (see "protective barrier").

"Protective barrier" means a barrier of radiation absorbing material used to reduce radiation exposure. The types of protective barriers are as follows:

1. "Primary protective barrier" means the material, excluding filters, intercepting the useful beam for protection purposes to reduce the radiation exposure so that it does not exceed two milliroentgens in any one hour.
2. "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to reduce radiation exposure so that it does not exceed two milliroentgens in any one hour.

"Radiation (ionizing)" means any electromagnetic or particulate radiation capable of producing ions, directly or indirectly, by interaction with matter.

"Qualified individual" means an individual who meets at least one of the following criteria for diagnostic x-ray equipment:

1. Certification by one of the following agencies in the specialty listed:

    i. The American Board of Radiology in Diagnostic Radiological Physics or Radiological Physics;

    ii. The American Board of Health Physics in Comprehensive Health Physics;

    iii. The American Board of Medical Physics in Diagnostic Imaging Physics or Medical Health Physics;

    iv. Certification issued by the Fellowship in the Canadian College of Physicists in Medicine which is equivalent to li or iii above; or

    v. Certification by other national certifying boards which may be recognized by the Commission on Radiation Protection where the person seeking recognition as a qualified individual has petitioned the CORP in writing and where the CORP has issued a written determination that the certification in question meets the criteria of a qualified individual pursuant to this subchapter;

2. A bachelor's degree from an accredited college in biology, chemistry, radiation sciences, physics, engineering, or mathematics and at least five years of professional technical experience in the field of radiological physics or in the use of medical of dental ionizing radiation-producing equipment;

3. A master's or doctorate degree in radiological health, radiation sciences, physics, chemistry, environmental sciences, engineering or a related field and at least two years of professional technical experience in the field of radiological physics or in the use of medical or dental ionizing radiation- producing equipment; or

4. Ten years of professional technical experience in the field of radiological physics or in a radiation protection activity. At least five years of the required health physics experience shall have been with medical or dental ionizing radiation-producing equipment.

"Scattered radiation" means radiation that, during passage through matter, has changed in direction or in energy.

"Secondary protective barrier" (see "protective barrier").

"Source-to-image distance" or "SID" means the distance from the radiation source to the center of the input surface of the image receptor.

"Source-to-skin distance" or "SSD" means the distance between the radiation source and the skin of the patient. It is also known as the target-to-skin distance.

"Stray radiation" means the sum of leakage and scattered radiation.

"Technique factors" means the following conditions of operation:

1. For capacitor energy storage equipment, the technique factors are peak tube potential in kV and quantity of charge in mAs;

2. For field emission equipment rated for pulsed operation, the technique factors are peak tube potential in kV and number of x-ray pulses;

3. For CT x-ray systems designed for pulsed operation, the technique factors are peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulse per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

4. For CT x-ray systems not designed for pulsed operation, the technique factors are potential in kV, scan time in seconds, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent ; and

5. For all other equipment, the technique factors are peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

"Uncertified unit" means an x-ray system comprised of components that are not subject to the regulations promulgated under Public Law 90-602, the Radiation Control Act of 1968, 21 Code of Federal Regulations, Chapter 1, Subchapter J-Radiological Health.

7:28-16.3 Dental radiographic equipment

(a) A person shall not operate or permit the operation of ionizing radiation-producing equipment used in the practice of dentistry unless the equipment meets the requirements listed below:

1. A diagnostic type protective tube housing shall be provided on the x-ray equipment.

2. Diaphragms or cones shall be used to collimate the useful beam and shall provide the same degree of protection as the diagnostic type protective tube housing.

3. For intraoral radiography, the diameter of the useful beam at the end of the cone in contact with the patient shall be no greater than seven centimeters (cm) (2.75 inches) when the source- to-skin distance is 18 cm (seven inches) or more. At SSD's less than 18 cm (seven inches), the diameter of the useful beam at the minimum SSD shall be no greater than six cm (2.36 inches).

4. A cone or spacer frame shall provide a source-to-skin distance of not less than 18 cm (seven inches) when the x-ray unit operates above 50 kVp or not less than 10 cm (four inches) when

the x-ray unit operates at or below 50 kVp.

5. All machines purchased, donated, or otherwise obtained after July 1, 1969, shall be equipped with open end cones.

6. The amount of total filtration permanently in the useful beam shall meet the minimum half-value layer (HVL) specified in the following table:

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TABLE 11

TABLE OF HALF-VALUE LAYERS FOR DENTAL UNITS

X-ray tube voltage (kilovoltage peak) Designed Operating Range (kVp)	Measured operating potential (kVp)	Minimum half-value layer(HVL) (mm of Al)
Below 50	30	1.5
	40	1.5
50 to 70	50	1.5
	60	1.5
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

7. For certified units, the x-ray tube voltage (kilovoltage peak) measured operating potential shall meet the manufacturer's specifications.

8. The exposure control switch shall be of the dead-man type.

9. The exposure control switch shall be provided with a timer that terminates the exposure after a preset time or preset exposure.

10. The exposure control switch button when depressed shall not energize the x-ray tube when the timer is in the "zero" or "off" position.

11. The exposure control switch shall be arranged to allow the operator to stand at least 1.83 meters (six feet) from the patient and well out of the path of the useful beam or to stand behind a protective barrier.

12. The x-ray control panel shall provide visual indication when-ever x-rays are produced.

13. For certified units, a signal audible to the operator shall be provided to indicate that the exposure has terminated.

14. For certified units, the coefficient of variation of the timer reproducibility shall not exceed 0.05 measured at any specific combination of technique factors.

15. For uncertified units, the coefficient of variation of the timer reproducibility shall not exceed 0.07 measured at any specific combination of technique factors.

16. For certified units, the timer accuracy shall meet or exceed the manufacturer's specifications. In the absence of manufacturer's specifications, the deviation shall not exceed 10 percent of the indicated value.

17. For certified units, the coefficient of variation of the radiation exposure reproducibility shall not exceed 0.05 measured at any specific combination of technique factors.

18. For uncertified units, the coefficient of variation of the radiation exposure reproducibility shall not exceed 0.07 measured at any combination of technique factors.

19. For uncertified units, the following requirements for radiation exposure linearity shall be met when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated:

    i. for equipment having independent selection of x- ray tube current (mA), the average ratios of exposure to the indicated milliampere-seconds product [(C/kg/mAs) or mR/mAs] obtained at any tube current settings shall not differ by more than 0.10 times their sum. This is: $[X1-X2] < 0.10(X1 + X2)$; where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two tube settings.

    ii. For equipment having a combined x-ray tube current-exposure time product (mAs) selector, the average ratios of exposure to the indicated milliampere-seconds product [(C/kg/mAs) or mR/mAs)] obtained at any two mAs selector settings shall not differ by more than 0.10 times their sum. This is: $[X1 - X2] < 0.10(X1 + X2)$; where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two mAs selector settings.

20. For certified units, the requirements for linearity is as follows:

    i. For equipment that allows a choice of x-ray tube current settings, the average ratios of exposure to the indicated milliampere-seconds product obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum: $[X1 - X2] < 0.10(X1 + X2)$; where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at each of two consecutive tube current settings or at two tube current settings differing by no more than a factor of two where the tube current selection is continuous.

    ii. For equipment having selection of x-ray tube current exposure time product (mAs), the average ratios of exposure to the indicated milliampere-seconds product [C/kg/mAs (or mR/mAs)] obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum: $[X1 - X2]$ $0.10(X1 + X2)$; where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at each of two consecutive mAs selector settings or at two mAs settings differing by no more than a factor of two where the mAs selector provides continuous selection.*

21. the mechanical support of the tube head and the cone shall maintain the exposure position without movement, unless the diagnostic type protective tube housing movement is a designed function of the x-ray system (for example, as in panoramic units).

7:28-16.4 Multiple dental radiographic tube installations

(a) No person shall use x-ray equipment in a multiple dental radiographic tube installation set up or cause it to be used unless the following requirements are met:

1. It shall be possible to activate only one dental radiographic tube at any one time.

2. Where two or more radiographic tubes are controlled by one exposure switch, the dental radiographic tube which has been selected shall be clearly indicated prior to initiation of the exposure. For certified units only, there shall be an indicator on both the x-ray control and at or near the dental radiographic tube housing assembly which has been selected.

3. It shall be possible to energize a dental radiographic tube from an exposure switch located at a specific dental radiographic tube's remote station only when that specific dental radiographic tube is selected.

4. It shall be possible to energize a dental radiographic tube from the main control panel exposure switch only when that specific dental radiographic tube is selected.

7:28-16.5 Cephalometric radiographic installations

(a) No person shall use x-ray equipment or cause it to be used to perform cephalometric radiographic procedures unless the following requirements are met:

1. The x-ray field in the plane of the image receptor shall not exceed each dimension of the image receptor by more than two percent of the source-to-image distance, when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition the center of the x-ray field shall be aligned with the center of the image receptor to within two percent of the SID, or there shall be a device provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

2. The x-ray unit used for cephalometric radiographs shall meet all the requirements of this subchapter with the exception of N.J.A.C. 7:28-16.3(a)3 and 7:28-16.6.

7:28-16.6 Panoramic radiographic installations

(a) No person shall use any panoramic radiographic unit or cause it to be used unless the following requirements are met:

1. The x-ray field in the plane of the image receptor shall not exceed each dimension of the image receptor by more than two percent of the SID, when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, the center of the x-ray field shall be aligned with the center of the image receptor to within two percent of the SID or there shall be a device provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

2. These units shall meet all the requirements of this subchapter with the exception of N.J.A.C. 7:28-16.3(a)3 and 7:28- 16.5

7:28-16.7 Structural shielding

(a) No person shall operate or permit the operations of x-ray equipment used in the practice of dentistry unless the following requirements are met:

1. Permanent structural shielding and protective barriers shall be used to ensure that no person

other than the patient being x-rayed receives a radiation dose in excess of two milliroentgens in any one hour.

2. When dental x-ray units are installed in adjacent areas of the same room, such units shall not be used simultaneously unless protective barriers are provided and used in the area between the units when necessary to comply with the radiation exposure limits in N.J.A.C. 7:28-6.

7:28-16.8 Radiation safety surveys

(a) No person shall operate or permit the operation of x-ray equipment used for dental radiography unless the installation meets the following requirements:

1. The registrant of a dental ionizing radiation-producing machine shall ensure that a qualified individual performs or supervises the performance of a radiation safety survey of the environs and submits a copy of the radiation safety survey report to the Department within 60 days of the date the machine is acquired. The registrant shall maintain the original survey report for as long as the machine is registered plus one year and shall make the original survey report available for review by the Department during any inspection;

2. The registrant of a dental ionizing radiation-producing machine shall ensure that a qualified individual performs or supervises the performance of a radiation safety survey of the environs when changes have been made to shielding, equipment, or equipment location which affect the radiation levels of the environs. A copy if the survey report shall be submitted to the Department within 60 days of the date of such change. The registrant shall maintain the original survey report for as long as the machine is registered plus one year and shall make the original survey report available for review by the Department during any inspection; and

3. The minimum requirements for the information to be include in the radiation safety survey report are as followings:

i. The name of the registrant of the installation at it appears on form VRH-001, address, telephone number, and room location of the unit;

ii. The New Jersey Registration Number, if available.

iii. The manufacturer, model number, generator serial number, control panel serial number, tube manufacturer, tube serial number, and tube housing number;

v. The date of survey;

vi. The survey instrument manufacturer, model number, and date calibrated;

vii. A diagram or floor plan of the area indicating the x-ray tube location, exposure switch location, normal operator position, lead shielding if present, wall, floor, and ceiling construction, labeling of all areas adjacent to the exposure rom including those above and below, and labeling of all areas as to occupancy and use;

viii. Records of the measurement of radiation exposure with a suitable phantom in the average patient position. Measurements shall be taken at the operator's position and all nearby locations which are normally occupied. For each measurements the kVp, mA, exposure time, instrument reading and correction made to the instrument reading (such as energy response, calibration, etc.) shall be recorded; and

ix. Exposure rates at each measured location shall be converted into Coulombs/kilogram/week or mR/week. Records shall include all assumptions of workload, use and occupancy factors used in the calculations.

7:28-16.9 Operating criteria

(a) No person shall operate a dental ionizing radiation- producing machine in such a manner as to expose human beings unless such person is a licensed practitioner or holds a valid license issued by the Department pursuant to N.J.A.C. 7:28-19 and the Radiologic Technologist Act, N.J.S.A. 26:2D-24 through 36.

(b) A person shall operate a dental ionizing radiation-producing machine in a manner consistent with the scope of practice defined on that person's license issued by the Department pursuant to N.J.A.C. 7:28-19.

7:28-16.10 Operating procedures

(a) All persons who operate or permit the operation of dental radiographic equipment shall comply with following operating procedures:

1. No individual other than the patient being x-rayed shall be in the path of the useful beam:

2. During each exposure the operator shall stand at least 1.83 meters (six feet) from the patient or behind a protective barrier;

3. The film shall not be held by the dentist, the operator, or the assistant during any radiographic exposure;

4. The diagnostic type protective tube housing and the cone shall not be hand held during exposures;

5. Fluoroscopy shall not be used in dental examinations; and

6. The registrant shall provide personnel monitoring equipment to and require that it be worn by each individual who enters a controlled area and receives or is likely to receive a dose in excess of 25 millirems in any period of seven consecutive days.

i. Each personnel monitoring device shall be assigned to and worn by only one person.

ii. Records of radiation exposure derived from the personnel monitoring device shall be kept in accordance with the requirements of N.J.A.C. 7:28-8.

iii. The registrant shall keep the personnel monitoring records at the facility. These records shall be kept in accordance with the requirements of N.J.A.C. 7:28-8. These records or true copy of same shall be produced for review by the Department during an inspection, and shall be submitted to the Department upon request.

iv. The personnel monitoring records shall be available to the employees.

SUBCHAPTER 17. INDUSTRIAL AND NONMEDICAL RADIOGRAPHY17. INDUSTRIAL AND NONMEDICAL RADIOGRAPHY

7:28-17.1 Scope

(a) This subchapter establishes radiation-safety requirements for persons utilizing sealed sources, radiographic-exposure devices or ionizing radiation-producing machines for industrial and nonmedical radiography.

(b) The requirements of this subchapter are in addition to the requirements of N.J.A.C. 7:28-1 through 7:28-13.

(c) This Subchapter does not apply to radiography in any of the healing arts.

Amended by R.1985 d.502, effective October 7, 1985.
See: 17 N.J.R. 1626(a), 17 N.J.R. 2389(a).
language change.

7:28-17.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Cabinet X-ray system" means an ionizing radiation-producing machine with the x-ray tube installed in an enclosure which, independent of existing architectural structures except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of x-radiation, including but not limited to all x-ray systems designed primarily for the inspection of carry-on baggage at air, railroad, and bus terminals, and similar facilities, and all x-ray systems designed primarily for the inspection of letters, periodicals, and packages in mailrooms. An x-ray tube used within a shielded part of a building or x-ray equipment which may temporarily or occasionally incorporate portable shielding, is not considered a cabinet x-ray system.

"External surface" means the outside surface of the cabinet x-ray system, including the high-voltage generator, doors, access panels, latches, control knobs, and other permanently mounted hardware and including the plane across any aperture or port.

"Industrial radiography" means the examination of the macroscopic structure of materials by nondestructive methods using sources of radiation.

"Shielded room radiography" means industrial radiography which is conducted in an enclosed room, the interior of which is not occupied during radiographic operations.

"Temporary job site" means any location where industrial radiography is performed other than the location(s) listed in a license or registration issued by the Department pursuant to N.J.A.C. 7:28-3 or 7:28-4.

New Rule R.1985 d.502, effective October 7, 1985.
See: 17 N.J.R. 1626(a), 17 N.J.R. 2389(a).
"Registration and licensing requirements" recodified to 17.3.
7:28-17.3 Registration and licensing requirements

(a) All owners of ionizing radiation-producing machines shall comply with N.J.A.C. 7:28-3.

(b) All owners of sealed sources or radiographic-exposure devices shall comply with N.J.A.C. 7:28-3 and 7:28-4.

Amended by R.1985 d.502, effective October 7, 1985.
See: 17 N.J.R. 1626(a), 17 N.J.R. 2389(a).
Recodified from 17.2; "Equipment control" recodified to 17.4.

7:28-17.4 Equipment control

(a) The permissible levels of radiation from radiographic-exposure devices and storage containers shall be as follows:

1. Radiographic-exposure devices measuring less than four inches from the sealed source storage position to any external surface of the device shall not produce a radiation level in excess of 50 milliroentgens per hour at least six inches from any point on the external surface of the device.

2. Radiographic-exposure devices measuring a minimum of four inches from the sealed source storage position to any external surface of the device and all storage containers for sealed sources or for radiographic-exposure devices shall not produce radiation levels in excess of 200 milliroentgens per hour at any point on the external surface and 10 milliroentgens per hour at one meter from any point on the external surface.

3. The radiation levels specified in 1 and 2 above are with the sealed source in the shielded or "off" position.

(b) Each radiation-producing machine shall be provided with a lock designed to prevent unauthorized use of the equipment.

(c) Each radiographic-exposure device and each storage container shall be provided with a lock or outer locked container designed to prevent unauthorized or accidental removal of a sealed source or its change from a shielded to an unshielded position. All ionizing radiation-producing machines, radiographic-exposure devices and storage containers shall be kept locked at all times except when under the direct surveillance of a radiographer or of a radiographer's assistant or as provided in N.J.A.C. 7:28-17.6(a).

(d) Locked radiographic-exposure devices and storage containers shall be physically secured to prevent tampering or removal by unauthorized personnel.

(e) The owner shall maintain sufficient calibrated and operable radiation-survey instruments to make physical radiation surveys as required by N.J.A.C. 7:28-17.6(c) and by N.J.A.C. 7:28-7. The requirements for the radiation-survey instruments are as follows:

1. Each radiation-survey instrument shall be calibrated at intervals not to exceed three months and the instrument shall be recalibrated after each servicing involving other than battery replacement. An operational check source test shall be performed on each radiation-survey instrument prior to its use.

2. Records shall be maintained of each date of calibration and the operational check source test results.

3. The instrumentation shall have a range such that two milliroentgens per hour through one roentgen per hour can be measured to a precision of plus or minus 20 per cent.

(f) The replacement of any sealed source fastened to or contained in a radiographic-exposure device and leak testing, repair, tagging, opening or any other modification of any sealed source shall be performed only by persons specifically authorized by the Department, a Federal agency or any Agreement state.

(g) Sealed sources are to be leak tested under the following conditions and requirements:

1. Each sealed source shall be tested for leakage at intervals not to exceed six months. In the

absence of a certificate from a transferor that a test has been made within the six months prior to the transfer, the sealed source shall not be put into use until tested.

2. The leak test shall be capable of detecting the presence of 0.005 microcuries of removable contamination on the sealed source. A test made at the nearest accessible point to the sealed source storage position may be an acceptable leak test.

3. Leak tests shall be carried out only by individuals and by procedures both of which require prior approval by the Department. Approval will be based upon a description of the following:

   i. Instrumentation to be used;

   ii. Method of performing test including points on equipment to be tested; and

   iii. Pertinent experience of person who will perform the test.

4. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Department.

(h) Requirements regarding any leaking sealed source shall be as follows:

1. Any test conducted pursuant to (g) above which reveals the presence of 0.005 microcuries or more of removable radioactive material shall be considered evidence that a sealed source is leaking.

2. The owner shall immediately withdraw any leaking sealed source above from use and shall cause it to be decontaminated and repaired in accordance with (f) or to be disposed of in accordance with N.J.A.C. 7:28-11.

3. Within five working days after obtaining results of the test performed pursuant to (g) above, a report shall be filed with the Department describing the equipment involved, the test results, and the corrective action taken.

(i) A sealed source which is not fastened to or contained in a radiographic-exposure device shall have permanently attached to it a durable tag at least one inch square, bearing the prescribed radiation caution symbol in conventional colors, magenta or purple on a yellow background, and at least the instructions: "Danger— Radioactive Material—Do Not Handle—Notify Civil Authorities if Found."

(j) Each owner shall conduct an ongoing inventory and keep a written record of each sealed source that is received, possessed, and used. This record shall include the date of receipt of each sealed source, the identity and quantity of the radioactive material contained within each sealed source, the date and to whom each sealed source is assigned and of the location at which each sealed source is to be used, the date that each sealed source is returned for storage at the owner's facility, the date that the source is returned for replacement, and the date of calibration.

(k) Each owner shall maintain current logs, which shall be kept available for inspection by the Department at the address specified in the license, showing for each radiation source the following information.

1. A description, or make and model number of the ionizing radiation-producing machine, or of the radiographic-exposure device or storage container in which the sealed source is

located;

2. The identity of the radiographer to whom assigned; and

3. The plant or site where used and dates of use.

(l) Each owner conducting industrial radiography at a temporary job site shall make the following records available at that site for inspection by the Department:

1. A copy of the owner's current license to possess or use radioactive materials issued by the Department pursuant to N.J.A.C. 7:28-4.

2. A copy of the owner's current registration of a radioactive material or ionizing radiation-producing machine issued by the Department pursuant to N.J.A.C. 7:28-3;

3. A copy of the owner's current license to possess or use radioactive materials issued by the United States Nuclear Regulatory Commission;

4. A copy of the owner's operating and emergency procedures prepared pursuant to N.J.A.C. 7:28-17.5(d);

5. A copy of N.J.A.C. 7:28;

6. Survey records required pursuant to N.J.A.C. 7:28- 17.6(c) for the period of operation at the site;

7. Daily pocket dosimeter records for the period of operation at the site required to be made pursuant to N.J.A.C. 7:28-17.5(e)2;

8. A copy of the latest instrument calibration and the original log of daily instrument operational check source test results for the specific devices in use at the site required to be made pursuant to (e)1 and 2 above; and

9. A copy of the record of leak test results made pursuant to (g)4 above.

Amended by R.1985 d.502, effective October 7, 1985.
See: 17 N.J.R. 1626(a), 17 N.J.R. 2389(a).
Recodified from 17.3 with substantive changes.

7:28-17.5 Personal radiation safety requirements for radiographers

(a) The owner shall not permit any person to act as a radiographer until such person:

1. Has been instructed by a qualified individual in the subjects outlined in (b) below and has demonstrated an understanding of those subjects by passing a written examination given by a qualified individual;

2. Has received copies of and instruction in the applicable sections of this Chapter and the owner's operating and emergency procedures required pursuant to (d) below, and demonstrated an understanding of this Chapter and the procedures specified therein; and

3. Has demonstrated competence to use the ionizing radiation-producing machines, radiographic-exposure devices, sealed sources, related handling tools and survey instruments which will be employed in his assignment.

(b) The outline of the course for radiographer's training is as follows:

1. Fundamentals of radiation safety:

    i. Characteristics of gamma and x-radiation;
    ii. Units of radiation dose and quantity of radioactivity;
    iii. Hazards of excessive exposure to radiation;
    iv. Levels of radiation from ionizing radiation-producing machines and radioactive materials;
    v. Methods of controlling radiation dose;

        (1) Working time;
        (2) Working distances;
        (3) Shielding.

2. Radiation detection instrumentation to be used:

    i. Use of ionizing radiation survey instruments:

        (1) Operation;
        (2) Calibration;
        (3) Limitations.

    ii. Survey techniques;
    iii. Use of personnel-monitoring equipment:

        (1) Film badges;
        (2) Pocket dosimeters;
        (3) Pocket chambers;

3. Radiographic equipment to be used:

    i. Ionizing radiation-producing machines;
    ii. Radiographic-exposure devices;
    iii. Storage containers;
    iv. Remote handling equipment.

4. The requirements of pertinent Federal and State regulations;
5. The owner's written operating and emergency procedures.

(c) The owner shall not permit any person to act as a radiographer's assistant until such person:

1. Has received copies of and instruction in the owner's operating and emergency procedures, required pursuant to (d) below, and has demonstrated an understanding of the procedures; and

2. Has demonstrated competence to use under the personal supervision of the radiographer the ionizing radiation-producing machines, radiographic-exposure devices, sealed sources, related handling tools and radiation-survey instruments which will be employed in his assignment; and

3. Has been instructed by a qualified individual in the subjects outlined in (b) above, and has

demonstrated an understanding of those subjects by written examination given by a qualified individual.

(d) The owner shall prepare written operating and emergency procedures which shall include instructions in at least the following:

1. The handling and the use of ionzing radiation-producing machines, sealed sources and radiographic-exposure devices to be employed such that no person is likely to be exposed to radiation doses in excess of the limits established in N.J.A.C. 7:28-6;

2. Methods and occasions for conducting radiation surveys;

3. Methods for controlling access to radiographic areas;

4. Methods and occasions for locking and securing ionizing radiation-producing machines, radiographic-exposure devices, storage containers and sealed sources;

5. Personnel monitoring and the use of personnel-monitoring equipment;

6. Transporting sealed sources to field locations, including packing of radiographic-exposure devices and storage containers in the vehicles, posting of vehicles, and control of the sealed sources during transportation;

7. Minimizing exposure of persons in the event of an accident;

8. The procedure for notifying proper persons in the event of an accident; and

9. Maintenance of records.

(e) The owner shall not permit any person to act as a radiographer or as a radiographer's assistant unless the owner has supplied to each such person and requires that each such person shall wear a film badge and either a pocket dosimeter or pocket chamber. The requirement for use of film badges, pocket dosimeters, and pocket chambers are as follows:

1. Pocket dosimeters and pocket chambers shall be capable of measuring doses from zero to at least 200 millroentgens.

2. Pocket dosimeters and pocket chambers shall be read and doses recorded daily.

3. A film badge will be assigned to and worn by only one person.

4. A film badge shall be immediately processed if a pocket chamber or pocket dosimeter is discharged beyond its range.

5. The film badge reports received from the film badge processor and records of pocket dosimeter and pocket chamber readings shall be maintained for inspection by the Department.

Amended by R.1985 d.502, effective October 7, 1985.
See: 17 N.J.R. 1626(a), 17 N.J.R. 2389(a).
Recodified from 17.4 with substantive changes.

7:28-17.6 Precautionary procedures in radiographic operations

(a) During each radiographic operation the radiographer or radiographer's assistant shall maintain a direct surveillance of the operation to protect against unauthorized entry into a high radiation area, except as follows:

1. Where the high radiation area is equipped with a control device which shall either cause the level of radiation to be reduced below that at which an individual might receive a dose of 100 millirems in one hour upon entry into the area, or shall energize a conspicuous visible and audible alarm signal in such a manner that the individual entering and the owner or the supervisor of the activity are made aware of the entry; or

2. Where the high radiation area is locked to protect against unauthorized or accidental entry.

(b) Notwithstanding any provisions in N.J.A.C. 7:28-10.8, areas in which radiography is being performed shall be conspicuously posted as required by N.J.A.C. 7:28-10.2 and 7:28-10.3.

(c) No radiographic operation shall be conducted unless calibrated and operable ionizing radiation-survey instrumentation as described in N.J.A.C. 7:28-17.4(e) is available and used at each site where radiographic exposures are made. In addition to the requirements of N.J.A.C. 7:28-7, radiation surveys shall be made and recorded as follows:

1. Physical radiation surveys shall be made as necessary during radiographic exposures to determine compliance with N.J.A.C. 7:28-6.

2. A physical radiation survey shall be made after each radiographic exposure employing a sealed source to determine that the sealed source has been returned to its shielded condition.

3. After radiographic operations employing a sealed source or sources have been completed, a physical radiation survey shall be made to determine that each sealed source is in its shielded condition prior to securing the radiographic-exposure device and storage container as specified in N.J.A.C. 7:28-17.4(a) and (c).

4. Clear and legible records shall be kept of the surveys that are required by (c) 1 and 3 above and maintained for inspection by the Department.

Amended by R.1985 d.502, effective October 7, 1985.
See: 17 N.J.R. 1626(a), 17 N.J.R. 2389(a).
Recodified from 17.5 with substantive changes.

7:28-17.7 Cabinet x-rays systems

(a) No person shall operate or permit the operation of a cabinet x-ray system unless such system meets the requirement of N.J.A.C. 7:28-17.1, 7:28-17.2, 7:28-17.3, and 7:28-17.7.

(b) No person shall operate or permit any other person to operate a cabinet x-ray system until the operator has received a copy of the operator's manual, has been trained in the operating procedures for the system, and has demonstrated competence in operating the system. The owner shall maintain a copy of the operator's manual in the proximity of the system.

(c) Each owner shall supply appropriate personnel monitoring equipment to and shall require that it be used by every individual who operates, makes "set-ups", or performs maintenance on a cabinet radiography unit.

(d) Radiation emitted from the cabinet x-ray system shall not exceed an exposure of 0.5

milliroentgen in one hour at any point five centimeters outside the external surface.

(e) No cabinet x-ray system shall be placed into operation until a radiation survey is made by a qualified individual demonstrating that the exposure level in (d) above is not exceeded. Where an operating system is subsequently modified, repaired or moved to a new location an additional survey shall be performed, and operation shall not resume until a survey demonstrates compliance with this limit. The owner shall perform such additional surveys as required by the Department or as determined by a qualified individual. The owner shall maintain a record of all surveys performed and shall make such records available to the Department for inspection.

(f) Safety interlocks shall be provided on cabinet x-ray systems as follows:

1. Each door of a cabinet x-ray system shall have a minimum of two safety interlocks installed in such a manner that the opening of any door would disconnect the energy supply circuit to the high-voltage generator.

2. Each access panel on a cabinet x-ray system shall have at least one safety interlock.

3. Following interruption of x-ray generation by the functioning of any safety interlock, a manually reset control button shall be activated before x-ray generation can resume.

4. Failure of any single component of the cabinet x-ray system shall not cause failure of more than one required safety interlock.

5. Safety interlocks shall be tested for operation at intervals not to exceed six months. A record of these tests shall be maintained for inspection by the Department.

(g) A cabinet x-ray system shall have a permanent floor.
Any support surface to which a cabinet x-ray system is permanently affixed may be deemed the floor of the system.

(h) Warning labels shall be provided on cabinet x-ray systems and shall meet the following requirements:

1. There shall be permanently affixed or inscribed on the cabinet x-ray system at the location of any controls which can be used to initiate x-ray generation a clearly legible and visible label bearing the statement or words having a similar meaning: “CAUTION: X-RAYS PRODUCED WHEN ENERGIZED”; and

2. There shall be permanently affixed or inscribed on the cabinet x-ray system adjacent to each port a clearly legible and visible label bearing the statement or words having a similar meaning: “CAUTION: DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED: X-RAY HAZARD”.

(i) All cabinet x-ray systems shall be provided with the following controls and indicators:

1. A key-actuated control to insure that x-ray generation is not possible with the key removed;

2. A control button or control switch to initiate and terminate the generation of x-rays other than by the functioning of a safety interlock or the main power control;

3. A warning light at the control button or control switch that indicates when and only when x-rays are being generated. This light shall be clearly labeled with the words: “X-RAY ON”;

4. A warning light which indicates when and only when x-rays are being generated. This warning light shall be visible from each door, access panel, and port and shall be clearly labeled with words: "X-RAY ON".

5. A meter which indicates the kilovoltage and current during the generation of x-rays at each x-ray control button or control switch unless the x-ray tube current is preset.

(j) Cabinet x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and similar facilities, shall be provided with means to insure that an operator is present at the control area in a position which permits surveillance of the ports and doors during the generation of x-radiation as follows:

1. During an exposure or preset succession of exposures of one-half second or greater duration, the system shall contain a mechanism to enable the operator to terminate the exposure or preset succession of exposures at any time.

2. During an exposure or preset succession of exposures of less than one-half second duration, there shall be a mechanism provided to allow completion of the exposure in progress but shall enable the operator to prevent additional exposures.

New Rule, R.1985 d.502, effective October 7, 1985.
See: 17 N.J.R. 1626(a), 17 N.J.R. 2389(a).

7:28-17.8 Shielded room radiography

(a) No person shall operate or permit the operation of any ionizing radiation-producing machine, radiographic-exposure device, or sealed source used in shielded room radiography unless the equipment, installation, and personnel meet the requirements of N.J.A.C. 7:28-17.1 through 7:28-17.6 and 7:28-17.8.

(b) No person shall operate or permit any person to operate an ionizing radiation-producing machine, radiographic-exposure device, or sealed source used in shielded room radiography until such operator has completed the following requirements:

1. The operator has met the requirements of N.J.A.C. 7:28-17.5;

2. The operator has received a copy of and instruction in N.J.A.C. 7:28-1 through 7:28-13 and 7:28-17 and a copy of the owner's operating and emergency procedures as required by N.J.A.C. 7:28-17.5(d) and has demonstrated an understanding of the procedures and regultions by written examination given by a qualified individual; and

3. The operator has demonstrated competence to operate appropriate safety systems.

(c) Each owner shall supply appropriate personnel monitoring equipment and shall require that it be used by every individual who operates, makes "set-ups," or performs maintenance on an ionizing radiation-producing machine, radiographic-exposure device, or sealed source used in shielded room radiography.

(d) The enclosed room in which shielded room radiography is conducted shall be shielded so that no location on the exterior exceeds the radiation levels and limits established in N.J.A.C. 7:28-6. No industrial radiography shall be conducted in a shielded room until a radiation survey is first made to insure compliance with these radiation levels and limits. A record of this survey shall be maintained and a copy shall be available for inspection by the Department.

(e) No person shall enter an enclosed room in which shielded room radiography is performed until after a physical radiation survey is conducted to determine whether the ionizing radiation producing machine is off or the radiographic-exposure device or the sealed source is in the shielded or "off" position. A record shall be maintained of the date and exposure rate measured for each physical radiation survey and shall be made available for inspection by the Department.

(f) The radiation surveys required in (d) and (e) above shall be made with a radiation survey instrument measuring radiation at the energies and at the exposure rates to be encountered. This instrument shall have an operational check source test conducted prior to each use and shall be calibrated at intervals not to exceed one year and shall be recalibrated after each servicing other than a battery replacement. Records shall be maintained of each date of calibration and the daily operational check and shall be made available for inspection by the Department.

(g) Adequate methods shall be provided to restrict the access of personnel and the public to any and all shielded room radiography areas to prevent the exposure of any person to radiation in excess of the level limits of N.J.A.C. 7:28-5, 7:28-6 and 7:28-17. No person is permitted to remain within the enclosed room where shielded room radiography is being performed.

(h) All ionizing radiation-producing machines, radiographic-exposure devices, and sealed sources used in shielded room radiography and all objects exposed thereto shall be confined within an installation or structure designed or intended for radiography and in which radiography is regularly performed in accordance with the following requirements:

1. A reliable interlock or other mechanism shall be installed at each means of access to the shielded room which will turn off the source(s) of radiation if a person tries to enter or open the door to the shielded room.

2. A door-fastening mechanism shall be installed so that the door to the shielded room can be opened from the inside at all times in case of emergency.

3. A visible and audible signal alarm system shall be installed within the shielded room which will be actuated at a reasonable length of time before the power to the radiation source can be activated which enables persons in the vicinity of the shielded room to take appropriate protective actions.

4. One or more scram or emergency buttons shall be installed at a highly visible and easily accessible location or locations within the shielded room that will terminate the power to the source of radiation. This scram or emergency button shall be installed so that it shall require manual resetting before the power to the source of radiation can be reactivated.

5. Each source of radiation used in shielded room radiography shall be provided with a lock at the control panel to prevent unauthorized use of the source.

6. If more than one source of radiation is used in the same shielded room, all such sources of radiation shall meet the requirements of 1-5 above.

New Rule, R.1985 d.502, effective October 7, 1985.
See: 17 N.J.R. 1626(a), 17 N.J.R. 2389(a).

SUBCHAPTER 18. MAJOR NUCLEAR FACILITIES18. MAJOR NUCLEAR FACILITIES

7:28-18.1 Scope

(a) The special requirements of this Subchapter shall apply to major nuclear facilities including nuclear reactors, nuclear fuel fabrication plants, nuclear fuel reprocessing plants, and nuclear waste handling or disposal facilities.

(b) These requirements are in addition to the requirements of other applicable Sections of this Chapter.

(c) The intent of this Section is to insure that individuals outside of these facilities receive no radiation exposures from environmental or direct radiation that are in excess of the limits of Sections 6.1 (Exposure of individuals in controlled areas) and 6.2 (Radiation levels outside controlled areas) of this Chapter.

7:28-18.2 Facility description and required monitoring program

(a) Any person desiring to construct a major nuclear facility within this State shall submit a general description of the proposed facility with a discussion of probable and maximum potential radioactive discharges. This description shall be submitted to the Department for evaluation, as early as possible, but not less than six months prior to the start of construction, and shall include the following:

1. A general description of the proposed facility;

2. The nature of and the proposed rates of discharge of radioactive contaminants to the environment and/or the nature of and amounts of radioactive materials subject to temporary or permanent storage;

3. The proposed methods of limiting the discharge of radioactive contaminants to the atmosphere;

4. The proposed methods of limiting the discharge of radioactive contaminants to ground or surface waters;

5. The proposed methods of disposal of radioactive or radioactively contaminated materials; and

6. Preliminary description of the proposed radiological monitoring program.

(b) As used in this section, the term "construction" includes pouring the foundation for, or the installation of, any portion of the permanent facility on the site, but does not include the following:

1. Site exploration, site excavation, preparation of the site for construction of the facility, including the driving of piles, and construction of roadways, railroad spurs, and transmission lines;

2. Procurement or manufacture of components of the facility; or

3. Construction of non-nuclear facilities (such as construction equipment storage sheds) for use in connection with the construction of the facility.

(c) Any person desiring to operate a major nuclear facility within this State shall develop an adequate program of radiological monitoring consistent with the hazard from actual or potential discharges. The proposed program shall be submitted to the Department for evaluation as to its

adequacy as early as possible but at least six months prior to the start of operation. The proposed radiological monitoring program shall include revised statements of the information required in (a) and (b) above, and it shall also include:

1. An analysis of the ability of the in-facility effluent monitoring system to measure the quantities and kinds of radioactive materials discharged under normal and under accident conditions;

2. An analysis of the ability to predict the effect of such releases on environmental contamination and radiation levels; and

3. A description of the off-site environmental monitoring system, if any, with the kinds of instruments, their sensitivity, and use.

7:28-18.3 Operation

(a) The owner of an existing major nuclear facility shall submit the information required in N.J.A.C. 7:28-18.2(c) (Facility description and required monitoring program) within one month of March 1, 1969, if he has not already done the effective equivalent of this.
(b) Operation of a major nuclear facility and its monitoring program shall be consistent with all provisions of this Chapter.

7:28-18.4 Emergency plans

The owner of every major nuclear facility shall make emergency operational plans in accordance with N.J.A.C. 7:28-1.5 (Emergency precautions). These plans shall be submitted to the Department prior to the start of operation.

7:28-18.5 Radiation incidents

The owner of every major nuclear facility shall report any radiation incident in accordance with N.J.A.C. 7:28-13 (Reports of Theft and Radiation Incidents).

SUBCHAPTER 19. MEDICAL EXPOSURE TO IONIZING RADIATION BY RADIOLOGIC TECHNOLOGISTS19. MEDICAL EXPOSURE TO IONIZING RADIATION BY RADIOLOGIC TECHNOLOGISTS

7:28-19.1 Purpose and responsibility

(a) The purpose of these rules and regulations is to prohibit and prevent excessive and improper exposure to ionizing radiation as set forth in P.L. 1981, c.295, Radiologic Technologist Act (N.J.S.A. 26:2D-24).

(b) Any person owning, using or handling sources of radiation directly or indirectly, shall be responsible for compliance with provisions of these rules and regulations.

7:28-19.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Board" means the Radiologic Technology Board of Examiners created pursuant to N.J.S.A. 26:2D-24 et seq.

"CAHEA" means the Committee on Allied Health Education Accreditation.

"Chest x-ray technologist (LRT(c))" means a person, other than a licensed practitioner, whose practice of radiologic technology is limited to the chest area for diagnostic purposes.

"Commission" means the New Jersey Commission on Radiation Protection.

"Commissioner" means the Commissioner of the Department of Environmental Protection.

"Dental x-ray technologist (LRT(D))" means a person other than a licensed practitioner, whose practice of radiologic technology is limited to dental radiography for diagnostic purposes.

"Department" means the New Jersey Department of Environmental Protection.

"Diagnostic x-ray technologist (LRT®)" means a person, other than a licensed practitioner, whose application of radiation to human beings is for diagnostic purposes.

"JRC/ERT" means Joint Review Committee in Education for Radiologic Technology.

"License" means a certificate issued by the Board authorizing the licensee to operate equipment emitting ionizing radiation on human beings for diagnostic or therapeutic purposes in accordance with the provisions of this subchapter.

"Licensed practitioner" means a person licensed or otherwise authorized by law to practice medicine, dentistry, dental hygiene, podiatry, chiropody, osteopathy or chiropractic.

"Licensed Radiologic Technologist, (LRT)" means any person licensed pursuant to this subchapter.

"Orthopedic x-ray technologist" means a person, other than a licensed practitioner, whose practice of radiologic technology is limited to the spine and extremities for diagnostic purposes only.

"Podiatric x-ray technology (LRT(P))" means a person, other than a licensed practitioner, whose practice of radiologic technology is limited to the operation of x-ray machines as used by podiatrists on the lower leg and foot area for diagnostic purposes only.

"Radiation therapy technologist (LRT(T))" means a person, other than a licensed practitioner, whose application of radiation to human beings is for therapeutic purposes.

"Radiologic technologist" means any person who is licensed pursuant to this subchapter, which shall include chest x-ray technologist (LRT(c)), dental x-ray technologist (LRT(D)), diagnostic x-ray technologist (LRT®), radiation therapy technologist (LRT (T)), podiatric x-ray technologist (LRT(P)), orthopedic x-ray technologist (LRT(O)), and urologic x-ray technologist (LRT(U)).

"Radiologic technology" means the use of equipment emitting ionizing radiation on human beings for diagnostic or therapeutic purposes under the supervision of a licensed practitioner.

"Student" shall mean any person who is enrolled in an approved course of study under the Radiologic Technologist Act (N.J.S.A. 26:2D-24 et seq.) or this subchapter.

"Unethical conduct" shall include, but not be limited to:

1. Engaging in the use of medical equipment emitting ionizing radiation or in the performance of any aspect of radiologic technology while in an intoxicated condition or under the influence of narcotic or any drugs which impair consciousness, judgement or behavior.

2. Willful falsification of records, or illegal destruction or theft of property or records relating to the practice of radiologic technology.

3. Failure to exercise due regard for the safety of life or health of the patient.

4. Unauthorized disclosure of information relating to a patient or his records.

5. Discrimination in the practice of radiologic technology against any individual because of race, religion, creed, color or national origin.

"Urologic x-ray technologist" means a person, other than a licensed practitioner, whose practice of radiologic technology is limited to the abdomen and pelvic area for urologic diagnostic purposes only.

Amended by R.1985 d.501, effective October 7, 1985.
See: 17 N.J.R. 1632(a), 17 N.J.R. 2393(a).
Added definition "podiatric x-ray technologist (LRT(P))."
Amended by R.1987 d.139, effective March 16, 1987.
See: 18 N.J.R. 236(a), 19 N.J.R. 449(b).
Added definitions "orthopedic x-ray technologist" and "urologic x-ray technologist" and amended "radiologic technologist."

7:28-19.3 General Provisions

(a) Except as hereinafter provided, no person other than a licensed practitioner or the holder of a license as provided in this subchapter shall use x-rays in such a manner as to expose human beings.

(b) The Board shall issue a license pursuant to this subchapter provided the applicant for a specific license has met all requirements as prescribed in N.J.A.C. 7:28-19.4.

(c) No person shall operate equipment emitting ionizing radiation in such a manner as to expose human beings or cause, suffer, allow or permit the use of such equipment in such a manner except as provided in this subchapter.

(d) No person shall operate equipment emitting ionizing radiation in such a manner as to expose human beings unless such person holds a valid license issued by the Board, pursuant to this subchapter, and unless such use is restricted to the scope of practice defined on the license.

(e) No person shall operate equipment emitting ionizing radiation in such a manner as to expose human beings unless the equipment complies with all relevant provisions of Chapter 28, Title 7 of the New Jersey Administrative Code (N.J.A.C. 7:28).

(f) The license of a radiologic technologist may be suspended for a fixed period or may be revoked, or the holder of such a license may be reprimanded or otherwise disciplined in accordance with the provisions and procedures filed in N.J.S.A. 26:2D-24 et seq. and N.J.S.A. 26:2D-57.

(g) The Board shall establish criteria and standards for programs of diagnostic, radiation therapy, dental, chest, podiatric, orthopedic, or urologic x-ray technology and approve these programs upon finding that the standards and criteria have been met.

(h) No person licensed to operate equipment emitting ionizing radiation shall be permitted in the primary beam, unless it is deemed essential for the specific examination by the licensed practitioner.

Amended by R.1985 d.501, effective October 7, 1985.
See: 17 N.J.R. 1632(a), 17 N.J.R. 2393(a).
Added podiatric in (g).
Amended by R.1987 d.139, effective March 16, 1987.
See: 18 N.J.R. 2361(a), 19 N.J.R. 449(b).
Added orthopedic or urologic to (g); (h) added.

7:28-19.4 Licensure procedure

(a) The Board shall admit to examination for licensing any applicant who shall pay to the Department a nonrefundable fee as specified in N.J.A.C. 7:28-19.12 and submit satisfactory evidence, verified by oath or affirmation, that the applicant:

1. At the time of application is at least 18 years of age;

2. Is of good moral character;

3. Has successfully completed a four year course of study in a secondary school approved or recognized by the State Board of Education, or passed an approved equivalency test; and

4. Has complied with the applicable requirements of (b) below.

(b) In addition to the requirements of (a) above, any person seeking to obtain a license in a specific area of radiologic technology must comply with the following applicable requirements:

1. Each applicant for a license as a diagnostic x-ray technologist (LRT®) shall have satisfactorily completed a 24-month course of study in diagnostic x-ray technology approved by the Board or its equivalent as determined by the Board.

2. Each applicant for a license as a radiation therapy technologist (LRT(T)) shall have satisfactorily completed a 24-month course in radiation therapy technology approved by the Board or the equivalent of such as determined by the Board.

3. Each applicant for a license as a chest x-ray technologist (LRT(c)) shall have satisfactorily completed the basic curriculum for chest radiography as approved by the Board or its equivalent as determined by the Board.

4. Each applicant for a license as a dental x-ray technologist (LRT(D)) shall have satisfactorily completed the curriculum for dental radiography as approved by the Board or its equivalent as determined by the Board.

5. Each applicant for a license as a podiatric x-ray technologist (LRT(P)) shall have satisfactorily completed the basic curriculum for podiatric radiography as approved by the Board or its equivalent as determined by the board.

6. Each applicant for a license as an orthopedic x-ray technologist (LRT(O)) shall have satisfactorily completed the basic curriculum for orthopedic radiography as approved by the Board or its equivalent as determined by the Board.

7. Each applicant for a license as a urologic x-ray technologist (LRT(U)) shall have satisfactorily completed the basic curriculum for urologic radiography as approved by the Board or its equivalent as determined by the Board.

(c) Each applicant for a license shall be required to pass an examination designated and approved by the Board pursuant to 26:2D-31a.

(d) The Board may accept in lieu of its own examination, a current certificate of The American Registry of Radiologic Technologists (ARRT), issued on the basis of a Registry examination satisfactory to the Board, or a certification or license as a radiologic technologist issued by another state provided that the standards are at least as stringent as those established by the

Board.

(e) The Board may accept in lieu of its own examination for Dental X-Ray Technologist LRT(D):

1. A current certificate of the New Jersey Board of Dentistry issued on the basis of satisfactory completion of the certification examination given by the Certifying Board of the American Dental Assistants' Association and any education requirements as may be prescribed by the New Jersey Board of Dentistry, provided that the above standards are at least as stringent as those established by the Board.

2. A current certificate issued by the Certifying Board of the American Dental Assistants' Association, provided that the standards of the above are at least as stringent as those established by the Board.

(f) All licenses are renewable as of December 31 of every even numbered year following the year of issuance. A license shall be renewed by the Board for a period of two years upon payment of a renewal fee as specified in N.J.A.C. 7:28-19.12, if the applicant has complied with all other applicable conditions or requirements established by the Board.

(g) Every radiologic technologist shall carry his license on his person at work. The license shall be displayed on request.

(h) An applicant who fails to pass the examination may reapply for the examination provided the applicant complies with the following:

1. Files a new application;
2. Pays the appropriate nonrefundable fee;
3. Submits the required documentation stated in (a) and (b) above; and
4. Satisfies any additional conditions or requirements set forth by the Board.

(i) The board may, in its discretion, issue a temporary license to any person whose license or relicense may be pending and in whose case the issuance of a temporary license may be justified by reason of special circumstances. A temporary license shall be issued only if the Board finds that its issuance will not violate the purposes of the act or tend to endanger the public health and safety. A temporary license shall expire 90 days after the date of the next examination if the applicant is required to take the same, or, if the applicant does not take the examination, then on the date of the examination. In all other cases, a temporary license shall expire when the determination is made either to issue or deny the applicant a regular license and in no event shall a temporary license be issued for a period longer than 180 days. No more than two temporary licenses may be issued to any individual.

Amended by R.1985 d.501, effective October 7, 1985.
See: 17 N.J.R. 1632(a), 17 N.J.R. 2393(a).
(b)5 added.
Amended by R.1987 d.139, effective March 16, 1987.
See: 18 N.J.R. 2361(a), 19 N.J.R. 449(b).
Substantially amended.

7:28-19.5 Proceedings for suspension or revocation

(a) The license of a radiologic technologist may be suspended for a fixed period, or may be revoked, or the technologist may be censured, reprimanded or otherwise disciplined, in accordance with the provisions and procedures defined in this subchapter, if after due hearing it is determined that he:

1. Is guilty of any fraud or deceit in his activities as a radiologic technologist or has been guilty of any fraud or deceit in procuring his license;

2. Has been convicted in a court of competent jurisdiction, either within or without this State, of a crime involving moral turpitude, except that if the conviction has been reversed and the holder of the license discharged or acquitted, or if he has been pardoned or his civil rights restored, the license may be restored to him;

3. Is or has been afflicted with any medical problem, disability, or addiction which, in the opinion of the board, would impair his professional competence;

4. Has aided and abetted a person who is not a licensed radiologic technologist or otherwise authorized pursuant to N.J.A.C. 7:28-19.4 in engaging in the activities of a radiologic technologist;

5. Has undertaken or engaged in any practice beyond the scope of the authorized activities of a radiologic technologist pursuant to the act;

6. Has falsely impersonated a duly licensed or former duly licensed radiologic technologist or is engaging in the activities of a radiologic technologist under an assumed name;

7. Has been guilty of unethical conduct as defined by rules promulgated by the commission;

8. Has continued to practice without obtaining a license renewal as required by this act;

9. Has applied ionizing radiation to a human being without the specific direction of a duly licensed practitioner as defined herein; or to any person or part of the human body outside the scope of his specific authorization;

10. Has acted or is acting as an owner, co-owner, or employer in any enterprise engaged in the application of ionizing radiation to human beings for the purpose of diagnostic interpretation, chiropractic analysis, or the treatment of disease;

11. Has expressed to a member of the public an interpretation of a diagnostic X-ray film or fluorescent image;

12. Has used or is using the prefix "Dr.", unless entitled to do so pursuant to a degree granted, the word "doctor" or any suffix or affix to indicate or imply that the radiologic technologist is a duly licensed practitioner as defined herein when not so licensed;

13. Is or has been guilty of incompetence or negligence in his activities as a radiologic technologist.

(b) Proceedings against any licensed radiologic technologist under this section shall be instituted by filing with the Board a written charge or charges in the form of a petition under oath against such licensed radiologic technologist.

1. The charges may be proffered by any person, corporation, association or public officer, or by the Department in the first instance.

2. A copy of the charges, together with a report of such investigation as the Department shall deem proper, shall be referred to the Board for its recommendation to the Commissioner.

(c) If the Commissioner determines the matter to be a contested case, he shall either designate three or more of the Board as a committee to hear and report on the charges and shall set a time and place for the hearing or shall refer the matter to the Office of Administrative Law for hearing before an administrative law judge, pursuant to the "Administrative Procedure Act," P.L. 1968, c.410 (N.J.S.A. 52:14B-1), as amended and supplemented. For the purpose of this section, the Board, its committee or the administrative law judge shall have power to issue subpoenas for the appearance of witnesses, and to take testimony under oath.

(d) Upon the conclusion of the hearing, the hearing officer shall make a written report of his findings and conclusions and shall transmit them together with his recommendation, to the Commissioner.

1. If the accused is found not guilty by the Commissioner, he shall order the charges dismissed.

2. If the accused is found guilty of the charges, the Commissioner shall, in his discretion, issue an order suspending, revoking or annulling the license or registration of the accused, or otherwise disciplining him.

(e) Where the license of any person has been revoked or annulled, under (c)2 above, the Board may after the expiration of two years accept an application for restoration of such license or registration.

7:28-19.6 Practice of radiologic technology

(a) The practice of diagnostic radiologic technology shall include: patient measurement, proper positioning for varied procedures to demonstrate the appropriate anatomical part on a radiograph as requested by a physician, selecting the correct technique factors on control panel, selecting proper distance and exercising proper principles of radiation protection and making x-ray exposures.

(b) The practice of radiation therapy technology shall include setting up the treatment position, delivering the required daily dose prescribed by the physician, certifying the record of the technical details of the treatment, selecting the required filter and treatment distance, making beam directional shells and molds, using diagnostic x-ray equipment for localization, assisting the physicist in calibration procedure, assisting in treatment planning procedures and exercising proper principles of radiation protection.

(c) The practice of dental x-ray technology shall include application of x-rays to human beings for diagnostic dental examination and exercising proper principles of radiation protection.

(d) The practice of chest x-ray technology shall include the application of x-rays to human beings restricted to the chest areas which shall be limited to posterior-anterior, anterior-posterior, oblique, lateral, decubitus and apical lordotic views of the chest for diagnostic purposes only, and exercising proper principles of radiation protection. It shall not include bronchograms, angiograms, cardiac catherization procedures, tomography and similar procedures.

(e) The practice of podiatric x-ray technology shall include patient measurement, proper positioning, selecting adequate technique factors on control panel, demonstrating anatomy as requested by physician, selecting proper distance, exercising proper principles of radiation protection and making x-ray exposures. The application of x-rays to a human being by podiatric x-ray technologists is restricted to the distal third lower leg (tibia/fibula) which shall include the ankle and foot area and shall not include the knee joint.

(f) The practice of orthopedic x-ray technology shall include application of x-rays to human beings to spine and extremities for diagnostic purposes. Such practice shall include patient measurement, proper positioning to demonstrate the appropriate anatomical part on a radiograph as requested by a physician, selecting the correct technique factors on control panel, selecting proper distance, exercising proper principles of radiation protection and making x-ray exposure.

(g) The practice of urologic x-ray technology shall include application of x-rays to human beings limited to the abdomen and pelvic area for urologic diagnostic purposes. Such practices shall include patient measurement, proper positioning to demonstrate the appropriate anatomical part on a radiograph as requested by a physician, selecting correct technique factors on control panel, selecting proper distance, exercising proper principles of radiation protection and making x-ray exposure.

Amended by R.1985 d.501, effective October 7, 1985.
See: 17 N.J.R. 1632(a), 17 N.J.R. 2393(a).
(e) added.
Amended by R.1987 d.139, effective March 16, 1987.
See: 18 N.J.R. 2361(a), 19 N.J.R. 449(b).
(f) and (g) added.

7:28-19.7 Supervision of a licensed practitioner

(a) Supervision of a Licensed Radiologic Technologist by a licensed practitioner shall require that such licensed practitioner, acting within the limits specified in the laws under which the practitioner is licensed shall determine that an x-ray exposure of a patient should be made and the part or parts of that patient's body which should be exposed, before a Licensed Radiologic Technologist may apply x-rays to a human being. Such supervision shall also require that only a licensed practitioner shall receive exposed and processed x-ray film for the purpose of diagnostic interpretation.

(b) Supervision by a licensed practitioner shall not require that a licensed practitioner oversee the Licensed Radiologic Technologist who is performing within the scope of his/her license as provided in N.J.A.C. 7:28-19.6

(c) Nothing in this section shall be construed to apply to students where use of radiation is governed under any other sections of this subchapter.

7:28-19.8 Students

(a) Candidates for admission to an educational program approved pursuant to N.J.S.A. 26:2D-24 shall satisfy the following minimum requirements:

1. Be of good moral character; and

2. Have successfully completed a four-year course of study in a secondary school approved by the State Board of Education or passed an approved equivalency test.

(b) All candidates for admission shall be required to submit a formal application. Candidates' high school and other credentials shall be obtained prior to selection. For accepted students these shall be kept on file at the sponsoring institution.

(c) A sponsoring institution shall report in writing to the Department the name and address of each

new student enrolled within 30 days and each student who has successfully completed the course of study within 30 days.

(d) The sponsoring institution shall maintain an adequate student/licensed radiologic technologist ratio as determined by the Board. In a limited license curriculum the LRT shall be licensed in the category the student is pursuing. A licensed diagnostic radiologic technologist (LRT®) may supervise students enrolled in any limited license curriculum.

(e) All students shall be provided with a personal radiation monitoring service, such as dosimeter or badge, during their period of attendance. Student exposure to radiation shall be within the occupational limits prescribed by N.J.A.C. 7:28-6.

1. Students shall routinely be informed of their most recent exposure readings and an attempt shall be made to find the cause and prevent recurrence of exposure which is deemed to be unnecessary.

2. Students shall not be permitted to be in the primary beam to hold patients during exposure, remain unnecessarily or unprotected in the x-ray room outside the control booth during exposure, or engaged in any other practices likely to result in a continuous and/or excessive exposure radiation.

(f) A sponsoring institution shall issue to each student who satisfactorily completes the course of study a formal certificate.

(g) A sponsoring institution shall issue to each candidate prior to admission a currently dated course catalog, bulletin, or other written statement, which shall describe the curriculum as a whole and the detailed course offered, list the faculty members with information regarding their qualifications, and inform each candidate of the amount and terms for payment of any tuition or other fees or expenses to be incurred. The policies relating to refund of fees, hours of attendance, vacation, holidays, absence, probation, uniforms, laundry, meals, stipends, rooms, transportation, and all requirements for satisfactory completion of the course of study shall be set forth clearly.

(h) All students shall have on them at all times while undergoing classroom or clinical education readily identifiable uniform marking or coloration or identification name plates indicative that they are students and not Licensed Radiologic Technologists. Inasmuch as schools differ, a variety of identification of students will be allowed, provided, however, that each school adopt and use a standard method of student identification approved by the Board of Examiners and registered with the Board.

Amended by R.1987 d.139, effective March 16, 1987.
See: 18 N.J.R. 2361(a), 19 N.J.R. 499(b).
Old (d) deleted and new (d) substituted.

7:28-19.9 Program approval

(a) The program in diagnostic x-ray technology shall be at least a 24-month course or its equivalent as determined by the Board. The Board may approve a program in diagnostic x-ray technology if it complies with the standards and criteria established by the Board. The curriculum for this course may follow CAHEA standard provided that the standards are not in conflict with Board policies.

(b) Accreditation Status Categories for Radiography and Radiation Therapy Programs shall be established by the Board and distributed to each program.

(c) The program of radiation therapy technology shall be at least a 24-month course of study or its equivalent as determined by the Board. The Board may approve a program of radiation therapy technology if it complies with the standards and criteria established by the Board. The curriculum for the course may follow CAHEA standards provided that the standards are not in conflict with the Board policies.

(d) The Board shall establish criteria and standards for programs of chest, dental, podiatric, orthopedic and urologic radiography and may approve such programs upon finding that the standards and criteria have been met.

(e) All applications for program approval and accreditation shall be made to the Board on forms provided by the Department.

(f) A sponsoring institution applying for program approval shall sup-ply all data necessary for a complete evaluation of its administration organization, faculty, physical facilities, student policies, curriculum and instruction and such other information and records as the Board may require.

(g) A site inspection of a sponsoring institution and its affiliates shall be made by an appointee of the Board or employee of the Department, except the Board may, in its discretion accept approval by the Joint Review Committee (JRC/ERT) in Education for Radiologic Technology and enter into a joint agreement with JRC/ERT to perform site inspections, in lieu of a separate State inspection.

(h) The Board may grant provisional accreditation based upon an agreement by a sponsoring institution to correct specified deficiencies within a period of time agreed to by the Board.

1. A sponsoring institution operating under a provisional accreditation shall within 15 days notify all enrolled students via certified mail of the institution's accreditation status.

2. All future correspondence and catalogs dispensed by such institutions regarding its programs shall include a statement regarding its provisional accreditation status.

(i) Accreditation and/or Provisional accreditation may be withheld or withdrawn, for failure to correct specified deficiencies and where the Department has determined that the institution is engaging in practices that are not consistent with acceptable standards for the operation of an educational institution. The sponsoring institution shall be notified in writing of the violation or violations resulting in withholding of accreditation or of the intent to withdraw accreditation and may, within 30 days of said notification, petition the Department in writing for a review thereof, and shall thereupon be given the opportunity to be heard on the violations by the Commissioner of Environmental Protection or shall be referred to the Office of Administrative Law. Hearings referred to the Office of Administrative Law shall be conducted in accordance with the provisions of the Administrative Procedure Act (N.J.S.A. 52:14B-1 et seq.) and the Uniform Administrative Procedure Rules (N.J.A.C. 1:1-1 et seq.).

(j) A sponsoring institution and its affiliates may be required at any time to submit or make available to the Department such information or records as the department or its authorized officers, employees or representatives requests and shall permit an authorized officer, employee or representative of the Department to perform site inspections. Failure to so perform shall be considered a violation of this section.

(k) A sponsoring institution whose accreditation has been withdrawn shall not be eligible for reaccreditation until such time as the deficiencies have been corrected.

(l) Accreditation may be withdrawn if the sponsoring institution does not have any students for a period of two successive years.

(m) A list of accredited programs and the criteria and standards as established by the Board will be available from the Department.

(n) To maintain accreditation, programs will be periodically reviewed by the Board to determine compliance with the standards and criteria as established by the Board. The Board may, at its discretion enter into agreement of settlement regarding its findings.

(o) Any violations of the standards may affect the program's accreditation status not withstanding any other remedy available to the Department.

(p) The sponsoring institution shall prepare in satisfactory written form and make use of detailed curriculum, a course outline for each required subject, and adequate lesson plans for classroom instruction. These materials shall be on file at the sponsoring institution and shall be accessible to any authorized officer, employee or representative of the Department.

(q) The sponsoring institution shall schedule classroom sessions in advance and give students sufficient notice thereof.

Amended by R.1985 d.501, effective October 7, 1985.
See: 17 N.J.R. 1632(a), 17 N.J.R. 2393(a).
Deleted "radiography" and substituted "podiatric."
Amended by R.1987 d.139, effective March 16, 1987.
See: 18 N.J.R. 2361(a), 19 N.J.R. 449(b).
Added orthopedic and urologic.

7:28-19.10 Use of medical ionizing equipment by students

(a) Students enrolled in and attending a Board approved program of radiologic technology may utilize the equipment emitting ionizing radiation in such a manner as to expose human beings for diagnostic or therapeutic purposes under the supervision of a licensed physician or a licensed radiologic technologist.

(b) Students enrolled in and attending a Board approved diagnostic, chest, dental, podiatric, orthopedic or urologic radiologic technology program may apply radiation to a human being for necessary diagnostic purposes only at the approved clinical facilities of the sponsoring institutions.

1. The operation of the x-ray equipment by a student shall be for the purpose of clinical experience in radiologic procedures and shall occur under the direct supervision of a licensed radiologic technologist in the appropriate category or a licensed practitioner.

2. Clinical supervision of the students shall be in accordance with Board policy.

(c) Students enrolled in and attending a New Jersey state approved college or college of medicine, osteopathy, dentistry, podiatry, or chiropractic may apply radiation to a human being for diagnostic purposes under the direct supervision of a licensed practitioner.

(d) Students enrolled in and attending an approved program of radiation therapy technology may apply radiation to a human being for necessary diagnostic (simulation) and therapeutic

procedures at the clinical facilities of such school and college for the purpose of clinical experience in the use of radiation therapy equipment. Clinical supervision of the students shall be in accordance with Board policy.

(e) The maximum hours of clinical and academic involvement for any student enrolled in an approved school of radiation therapy technology or diagnostic x-ray technology in New Jersey shall not exceed a total of 40 hours per week.

Amended by R.1985 d.501, effective October 7, 1985.
See: 17 N.J.R. 1632(a), 17 N.J.R. 2393(a).
Added "podiatric" in (b).
Amended by R.1987 d.139, effective March 16, 1987.
See: 18 N.J.R. 2361(a), 19 N.J.R. 449(b).
Added orthopedic and urologic.

7:28-19.11 Criteria and standards

The Board will establish criteria and standards for educational programs in each licensing category. These standards will be printed and available from the Department of Environmental Protection, Bureau of Radiation Protection, Trenton, New Jersey 08625.

7:28-19.12 Fees

(a) Any person who submits an application for a license or license renewal to the Department shall include as an integral part of said application a service fee as follows:

1. Application Fee: $30.00
2. Examination Fee: $30.00
3. Renewal Fee: $20.00

(b) The fees accompanying the application or license renewal shall be in the form of a certified check or money order made payable to the State of New Jersey.

1. The fees submitted to the Department are not refundable.
2. The fees accompanying the initial application or renewal shall be mailed to:

State of New Jersey
Department of Environmental Protection
Bureau of Collection and Licensing Unit
CN 402
Trenton, New Jersey 08625

New Rule, R.1987 d.139, effective March 16, 1987.
See: 18 N.J.R. 2361(a), 19 N.J.R. 449(b).

SUBCHAPTER 20 PARTICLE ACCELERATORS FOR INDUSTRIAL AND RESEARCH USE20 PARTICLE ACCELERATORS FOR INDUSTRIAL AND RESEARCH USE

7:28-20.1 Scope

(a) This Subchapter establishes requirements and procedures for the registration and use of all particle accelerators, with the exception of those regulated by N.J.A.C. 7:28-14 and 15.

(b) A person shall not operate or permit the operation of a particle accelerator unless the equipment and installation meet the applicable requirements of this subchapter.

(c) In addition to the requirements of this subchapter, all registrants of particle accelerators are subject to all other applicable requirements of N.J.A.C. 7:28-1 through 11 and 13.

7:28-20.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise:

"Direct supervision" means guidance and instruction by the qualified machine operator who is physically present, is watching the operation of the particle accelerator, and is available for immediate assistance;

"Electron microscope" means a machine that accelerates electrons for the purpose of producing highly magnified images of materials and material surfaces;

"kVp" means kilovolt peak;

"Particle accelerator" means any machine that accelerates charged particles (electrons, protons, deuterons, or other charged particles, etc.) in a vacuum and discharges the resulting particulate or other radiation but which does not meet the specifications of machines currently regulated under N.J.A.C. 7:28-14 through 16; particle accelerators include but are not limited to machines used for research, irradiation, or other purposes; such machines include, but are not limited to, potential-drop accelerators, electron linear accelerators, cyclotrons, betatrons, microtrons, ion implant accelerators, and electron microscopes; particle accelerators do not include high voltage generators, televisions, video display terminals, cathode ray tubes or other similar devices whose primary purpose is not the production of a useful charged particle beam;

"Particle accelerator facility" means the location at which one or more particle accelerators are installed and are operated under the same administrative control;

"Particle accelerator safety officer" or "PASO" means the person who is appointed and authorized by the registrant to act on the registrant's behalf to implement and maintain the particle accelerator radiation protection program for the registrant's facility;

"Performance test" means a procedure which is performed to assure that an instrument continues to perform its intended function;

"Qualified machine operator" means a person who meets the requirements of N.J.A.C. 7:28-20.6(a);

"Radiation protection committee" means a group consisting of at least three individuals appointed by the registrant who identify radiation safety problems, initiate, recommend, or provide corrective action plans, and verify the implementation of corrective actions. One member of this committee shall be the particle accelerator safety officer and one member shall be a representative of management. The remaining members shall be appointed at the discretion of the registrant;

"Scattered radiation" means radiation that, during passage through matter, has changed in direction or in energy;

"Stray radiation" means the sum of leakage and scattered radiation.

7:28-20.3 Registration requirements

A person shall not possess, control, use or cause a particle accelerator or an electron microscope to be used unless it has been registered with the Department pursuant to N.J.A.C. 7:28-3, unless the particle accelerator or electron microscope is incapable of operating at more than 5 kVp and does not produce radiation greater than 0.5 millirem per hour at any readily accessible point five centimeters

from its surface.

7:28-20.4 General requirements for a particle accelerator facility

(a) Particle accelerators not capable of operating at more than 30 kVp shall be exempt from the requirements of (b) through (f) below and N.J.A.C. 7:28-20.5 through 20.12 provided that the initial or repeat radiation protection survey does not yield radiation levels greater than 0.5 millirem per hour using maximum operating conditions of operation as measured five (5) centimeters from any accessible surface.

(b) A registrant shall not permit a particle accelerator to be operated unless the person operating the particle accelerator has met the requirements of N.J.A.C. 7:28-20.6(a).

(c) A registrant shall not use a particle accelerator or cause it to be used unless the equipment, facilities, operating procedures and emergency procedures are adequate to minimize danger to property and to public health and safety.

(d) The registrant of a particle accelerator facility shall appoint a Particle Accelerator Safety Officer (PASO) who is authorized to act on behalf of the registrant to implement and maintain a radiation safety program for the particle accelerator facility. The PASO may be either a full-time employee of the registrant or a consultant hired by the registrant. The registrant shall hold the final responsibility for the safe operation of the facility in accordance with all pertinent provisions of this Chapter.

(e) A particle accelerator safety officer shall meet at least one of the following five criteria:

1. Certification in health physics by the American Board of Health Physics or certification in therapy physics and /or radiological physics by the American Board of Radiology;

2. A Bachelor's degree from an accredited college in biology, chemistry, radiation sciences, physics, engineering or mathematics and six years of professional technical experience in the field of radiological health or in a radiation protection activity. At least one year of the required health physics experience shall have been with a particle accelerator of a type similar to that with which the PASO will be working;

3. A master's degree in radiological health, radiation sciences, physics, chemistry, environmental sciences, engineering or a related field and at least five years of professional technical experience in the field of radiological health or in a radiation protection activity. At least one year of the required health physics experience shall have been with a particle accelerator of a type similar to that with which the PASO will be working;

4. A doctorate degree in radiological health, radiation sciences, physics, chemistry, environmental sciences, engineering or a related field plus four years of professional technical experience in the field of radiological health or in a radiation protection activity. At least one year of the required health physics experience shall have been with a particle accelerator of a type similar to that with which the PASO will be working; or

5. Ten years of professional technical experience in the field of radiological health or in a radiation protection activity. At least five years of the required health physics experience shall have been with a particle accelerator of a type similar to that with which the PASO will be working.

(f) A particle accelerator safety officer in a facility where the particle accelerators are only electron microscopes shall comply with the requirements set forth in subsection (e) above or shall have

received a bachelor's degree from an accredited college in a biological or physical science and shall have passed at least one course in radiation safety offered by an accredited college.

(g) The registrant of a particle accelerator shall appoint a radiation protection committee whose approval shall be required for implementation of procedures for the use of each particle accelerator. The PASO shall be a member of this committee.

7:28-20.5 Use of particle accelerators on humans

(a) A registrant shall not use a particle accelerator or cause it to be used for the intentional irradiation of humans without first sending to the Department a written request stating the registrant's reasons for this use of the particle accelerator and the manner in which it will be used, and obtaining written approval from the Department.

(b) A registrant shall not use a particle accelerator or cause it to be used for the intentional irradiation of humans unless the equipment meets the requirements of this subchapter and N.J.A.C. 7:28-14.

7:28-20.6 Training program on the safe use of each particle accelerator

(a) The registrant shall establish and maintain a training program on the safe use of each particle accelerator. The registrant shall not permit any person to operate the particle accelerator until that person has successfully completed the training program consisting of the ten items set out below. The registrant shall ensure that the training program is conducted under the direction of the PASO, or an individual with equivalent qualifications, in conjunction with the qualified machine operator and that the program shall include all of the following:

1. Instruction in the types, characteristics, location, and levels of radiation produced by the particle accelerator;

2. Instruction in the units of radiation exposure, dose, dose equivalent, and quantity of radioactivity associated with the particle accelerator;

3. Instruction in the biological effects of ionizing radiation;

4. Instruction in the methods used to prevent radiation exposure at the particle accelerator facility, including, but not limited to, time, distance, shielding, interlock system, safety procedures and radiation monitoring equipment;

5. Instruction in the use and care of personnel monitoring equipment employed at the particle accelerator facility;

6. Instruction on the location and use of all operating controls for the particle accelerator;

7. Instruction on the requirements of this subchapter and N.J.A.C. 7:28-1 through 11 and 13;

8. Instruction in the facility's written operating and emergency procedures;

9. An examination testing the operator's knowledge of the requirements of 1 through 8 of this subsection. The examination shall be of sufficient depth to demonstrate that the operator has received instruction in each of the items listed above and has an understanding of the items at a level which permits the operator to use the particle accelerator in a manner consistent with the overriding goal of minimizing danger to public health and safety; and

10. At least 100 documented hours of on-the-job training under the direct supervision of a qualified machine operator and certified in writing by the PASO. The registrant shall maintain this documentation and certification for five years at the particle accelerator facility. These records shall be produced for review by the Department during an inspection and shall be submitted to the Department upon request. If, in the opinion of the PASO, the requirement of 100 hours of on-the-job training is too stringent for a particular particle accelerator, then the PASO shall submit a report documenting the number of hours of on-the-job training needed to become a qualified operator to the Department for approval.

(b) The registrant shall require each operator to become requalified not less than once every three years by completing a refresher training course covering the requirements of (a) 1 through 9 of this section. The registrant shall maintain a record of each individual's completion of the refresher training course for five years at the particle accelerator facility. These records shall be produced for review by the Department during an inspection and shall be submitted to the Department upon request.

(c) A registrant may permit a person to function as an operator's assistant under the direct supervision of a qualified machine operator until that person has completed a training course covering the requirements of (a)1 through 10 of this section.

(d) The registrant shall maintain records of the operator's training program, including a copy of the examination, for at least five years at the particle accelerator facility. These records shall be produced for review by the Department during an inspection and shall be submitted to the Department upon request.

(e) Prior to operation of any particle accelerator after February 3, 1992, the registrant shall document in writing the name of each individual who operated a particle accelerator prior to February 3, 1992 and whom the PASO and the Radiation Protection Committee have certified as the first qualified machine operator for each particle accelerator. The registrant shall maintain this documentation for five years at the particle accelerator facility and shall produce it for review by the Department during an inspection. After February 3, 1992, an individual is required to complete all items in (a) above in order to become a qualified machine operator.

(f) When a new particle accelerator facility commences operation or places into operation a newly invented particle accelerator, the PASO and the Radiation Protection Committee shall document in writing the name and qualifications of the individual whom they have certified as the first qualified machine operator. Any subsequent machine operator shall be subject to the provisions of subsection (a) of this section.

7:28-20.7 Shielding design and radiation area survey requirements for a particle accelerator

(a) A person shall consult with an individual with qualifications equivalent to those specified in N.J.A.C. 7:28-20.4(e) with respect to the health physics considerations in the design of a particle accelerator installation. The original record of this consultation, including the shielding design, shall be maintained at the particle accelerator facility for the life of the unit and shall be produced for review by the Department during an inspection and a copy submitted to the Department along with the registration form. This section shall apply to those particle accelerators planned for installation after the effective date of this subchapter.

(b) A registrant shall not install a particle accelerator unless such unit is designed and constructed with primary and/or secondary protective barriers as are necessary to comply with the permissible dose rates, radiation levels and concentrations specified in subchapter 6 of this chapter.

(c) A registrant shall ensure that a radiation survey of controlled areas and of adjacent areas is performed by the PASO or by a qualified individual under the supervision of the PASO to ensure that radiation exposure of individuals conforms to the requirements of subchapter 6 of this chapter, and an inspection is performed of the health physics aspects of the facility when the particle accelerator is first capable of producing radiation, but before the particle accelerator is used for any purpose other than installation or assembly of the particle accelerator, or the conducting of radiation surveys and health physics inspections.

(d) The registrant shall ensure that a written report of the radiation survey and health physics inspection is prepared by the PASO or by a qualified individual under the supervision of the PASO for review by the registrant. The registrant shall maintain these reports for the duration of the life of the machine at the particle accelerator facility.

(e) Prior to operation of the particle accelerator the registrant shall implement or cause to be implemented the recommendations listed in the radiation survey and health physics report, including any special limitations which are necessary to comply with the requirements of this chapter. The registrant shall ensure that a follow-up radiation area survey of controlled areas and of adjacent areas is performed by the PASO or by a qualified individual under the supervision of the PASO and a follow-up health physics inspection is conducted to ensure that the recommendations as implemented meet the requirements of this chapter. The registrant shall ensure that a written report of the follow-up radiation survey and the follow-up health physics inspection is prepared by the PASO or under the supervision of the PASO for review by the registrant.

(f) The registrant shall submit a copy of the radiation survey and health physics inspection report required by subsection (d) and (e) of this section to the Department within 30 days of the date of the survey and health physics inspection report, and shall maintain the original radiation survey and health physics inspection report for the duration of the life of the machine at the particle accelerator facility. The radiation survey and health physics inspection reports shall be produced for review by the Department upon request.

(g) The requirements of subsection (c) of this section shall be followed when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas which could affect radiation exposure of any individual and at intervals not to exceed one year.

(h) The registrant shall maintain at least two radiation survey instruments suitable for measuring all levels and energies of radiation capable of being produced by the particle accelerator. At least one of these radiation survey instruments shall be calibrated, operable, and easily accessible at the facility for use at all times.

(i) A registrant shall not use or cause a radiation survey instrument to be used unless:

1. A performance test is conducted on the survey instrument prior to each day's use;

2. The survey instrument is calibrated at intervals not exceeding one year using a nationally recognized calibration criteria;

3. The survey instrument is recalibrated each time it is serviced or repaired. If the service involved only a battery replacement, the survey instrument does not have to be recalibrated; and

4. The calibration procedure has been performed by a qualified individual using nationally

recognized calibration procedures which conform to those of the National Institute of Standards and Technology. These procedures shall identify the calibration source used. Results of each calibration of the survey instrument shall be maintained at the particle accelerator facility for five years. The record of these results shall be produced for review by the Department during an inspection and shall be submitted to the Department upon request.

7:28-20.8 Particle accelerator controls and interlock systems

(a) A registrant shall not operate or cause a particle accelerator to be operated unless each personnel entrance into a particle accelerator's high radiation area or exclusion area has been provided with the safety features listed below:

1. Clearly identified and easily discernible instrumentation, readouts and controls pertinent to the production of radiation;

2. A clearly identifiable switch on the accelerator control console which requires a positive, intentional action on the part of the operator for routine use in turning the particle accelerator beam on and off;

3. A personnel safety interlock system designed with a personnel safety interlock circuit. The personnel safety interlock system shall include a visual search procedure to clear personnel from the controlled area and high radiation areas prior to the production of radiation;

4. Personnel safety interlocks on all entrances into a controlled area and other high radiation areas that automatically terminate the production of radiation upon entry;

5. Circuitry such that when a safety interlock has been tripped, it shall only be possible to resume operation of the particle accelerator by manually resetting the controls, first at the position where the interlock has been tripped, and thereafter at the main control console;

6. Circuitry such that each personnel safety interlock shall allow its individual operation independent of all other interlocks;

7. Safety interlocks designed with fail-safe characteristics so that any defect or component failure in the interlock system prevents the production of radiation; and

8. A clearly identifiable emergency radiation cutoff switch shall be located in all high radiation areas and at the control console. Each cut-off switch shall include a manual reset switch so that the particle accelerator cannot be restarted from the accelerator control console without resetting the cut-off switch.

(b) A registrant shall not cause or allow a person to bypass intentionally an interlock which permits the production of radiation, unless such bypass fulfills all of the following conditions:

1. It is authorized for and limited to a specified time period by the radiation protection committee or PASO in writing prior to the bypass;

2. It is recorded in a permanent log;

3. It is accompanied by the posting of a prominent notice at the particle accelerator control console and at each personnel entrance being bypassed; and

4. It is terminated as soon as the need for the by-pass no longer exists as determined by the

PASO.

7:28-20.9 Warning devices

(a) A particle accelerator shall not be operated unless the registrant has equipped all locations designated as high radiation areas and all entrances to such locations with clearly observable warning lights that operate when, and only when, radiation is being produced, and which shall be labeled to indicate that, when lit, radiation is being produced. The warning lights shall be included in the electrical circuitry of the particle accelerator such that when a warning light is not lit radiation cannot be produced in any area where personnel may be present.

(b) A particle accelerator shall not be operated unless the registrant has provided in each high radiation area audible and visual warning devices which shall be interlocked and activated for at least 30 seconds prior to production of radiation by the particle accelerator. Such warning devices shall be clearly discernible and labeled as to their function. The audible warning device alarm may be terminated once the high radiation area has been secured. Particle accelerator facilities designed and approved for human exposure are excluded from this requirement.

(c) A particle accelerator shall not be operated unless the registrant has identified barriers, temporary or otherwise, and pathways leading to high radiation areas in accordance with the labeling, posting and control requirements of N.J.A.C. 7:28-10.

7:28-20.10 Operating procedures

(a) A registrant shall not operate or permit the operation of a particle accelerator unless all of the following requirements have been met:

1. The particle accelerator is equipped with a means (such as, but not limited to, a locked console or a locked room) to prevent its unauthorized use;

2. The safety interlock system is not used to turn off the particle accelerator beam except in an emergency or for testing the operation of the interlock;

3. The operation of all safety and warning devices, including interlocks, is tested by the qualified machine operator and the test results recorded at intervals not to exceed 30 days and such testing is verified in writing by the PASO at intervals not to exceed 90 days; each safety and warning device shall be listed separately in a log in which the test results are recorded; the log shall be maintained for five years at the particle accelerator facility and shall be produced for review by the Department during an inspection;

4. Electrical circuit diagrams accurately reflecting the current status of the particle accelerator and the associated interlock systems are available to the operator and for inspection by the Department. The electrical circuit diagrams shall be reviewed and/or revised at intervals not to exceed one year by the qualified machine operator and the PASO shall verify in writing at intervals not to exceed one year that the review and/or revision was performed; the registrant shall maintain a record of such review for five years at the particle accelerator facility, and the record shall be produced for review by the Department during an inspection;

5. A copy of the current operating and emergency procedures is prepared under the direction of the PASO and maintained at the particle accelerator control panel. These operating and emergency procedures shall be reviewed and/or revised under the direction of the PASO at intervals not to exceed one year. The registrant shall maintain a record of such review with the current operating and emergency procedures at the accelerator facility for the life of the particle accelerator. This record shall be produced for review by the Department during an

inspection; and

6. The written operating and emergency procedures address the methods used to prevent radiation exposure at the particle accelerator facility. The procedures shall include, but not be limited to, the following topics:

   i. The location and operation of the interlock systems;
   ii. The safety procedures that apply to each particle accelerator;
   iii. The types and use of personnel monitoring equipment;
   iv. The procedures and personnel requirements for changing the target;
   v. The handling and disposal procedures for disposing of a target;
   vi. The procedures for surveys and wipe tests; and
   vii. The emergency procedures regarding personnel and machine operations applicable to each particle accelerator.

7:28-20.11 Radiation area and personnel monitoring requirements

(a) The registrant shall identify in writing all types of radiation that will be produced, both primary and secondary, by the particle accelerator and the monitoring equipment selected to measure all the corresponding types and energies of radiation levels. The registrant shall maintain these records at the particle accelerator facility for five years. These records shall be produced for review by the Department during an inspection and shall be submitted to the Department upon request.

(b) The registrant shall continuously monitor the radiation levels in or at the entrance to all high radiation areas. The area monitoring devices shall have fail-safe characteristics and shall be capable of providing a remote and local readout with visual and/or audible alarms at the accelerator control panel, any entrance to high radiation areas, as well as at other appropriate locations determined by the PASO so that a person entering the high radiation area or present therein becomes aware of the existence of the hazard.

(c) The registrant shall have all area monitors calibrated at intervals not to exceed twelve months and after each servicing and repair according to written procedures established by the PASO. The calibration procedures and records shall be maintained for five years at the particle accelerator facility. These procedures and records shall be produced for review by the Department during an inspection and shall be submitted to the Department upon request.

(d) If the PASO has identified airborne particulate radiation as a primary or secondary product of a particle accelerator as required pursuant to (a) above, then surveys shall be performed by the PASO or other qualified individual under the supervision of the PASO at least once in each quarter of the calendar year to determine that the amount of airborne particulate radioactivity present in controlled areas is in compliance with N.J.A.C. 7:28-6. Where survey results indicate noncompliance with N.J.A.C. 7:28-6, use of the particle accelerator shall be immediately discontinued and remedial measures to bring the particle accelerator into compliance with N.J.A.C 7:28-6 shall be taken. Use of the particle accelerator is prohibited until such time as new surveys show that compliance with N.J.A.C. 7:28-6 has been achieved. The results of the surveys shall be maintained for five years at the particle accelerator facility. Survey results shall be produced for review by the Department during an inspection and shall be submitted to the Department upon request.

(e) If the PASO has identified removable contamination as a primary or secondary product of a particle accelerator as required pursuant to (a) above, then wipe tests shall be performed by the PASO or other qualified individual under the supervision of the PASO upon initial use of the particle accelerator and, thereafter, at least every six months to determine the degree of

removable contamination in the target area and other pertinent areas to ensure compliance with N.J.A.C. 7:28-9. Where wipe test results indicate noncompliance with N.J.A.C. 7:28-9, use of the particle accelerator shall be immediately discontinued and remedial measures to bring the particle accelerator into compliance with N.J.A.C. 7:28-9 shall be taken. Use of the particle accelerator is prohibited until such time as new wipe tests show that compliance with N.J.A.C. 7:28-9 has been achieved. The results of the wipe tests shall be maintained for five years at the particle accelerator facility. Wipe test results shall be produced for review by the Department during an inspection and shall be submitted to the Department upon request.

(f) Surveys shall be made by the PASO or other qualified individual under the supervision of the PASO upon initial use of the particle accelerator and, thereafter, not less than once annually, to determine the levels of radiation resulting from activation of the target and other pertinent areas to determine compliance with N.J.A.C. 7:28-6 and 9. Where test results indicate noncompliance with N.J.A.C. 7:28-6 and 9, use of the particle accelerator shall be immediately discontinued and remedial measures to bring the particle accelerator into compliance with N.J.A.C. 7:28-6 and 9 shall be taken. Use of the particle accelerator is prohibited until such time as test results show that compliance with N.J.A.C. 7:28-6 and 9 has been achieved. The results of the surveys shall be maintained for five years at the particle accelerator facility. Surveys shall be produced for review by the Department during an inspection and shall be submitted to the Department upon request.

(g) The PASO shall develop procedures for performing surveys and wipe tests required by (d), (e), and (f) above. These procedures shall be in writing and shall be kept at the particle accelerator facility. These procedures shall be produced for review by the Department during an inspection and shall be submitted to the Department upon request. The survey and wipe test procedures shall contain, but shall not be limited to, the instrumentation to be used in conducting surveys and wipe tests, the method of performing the survey and wipe test (for example, points on the equipment from where wipe samples will be taken and method of obtaining the wipe sample), and method of calculation of survey and wipe test results.

(h) The registrant shall supply all individuals with and shall require these individuals to use and wear appropriate personnel monitoring equipment as listed below when entering the area which has been defined as a high radiation area while the particle accelerator is in operation:

1. Direct reading dosimeters capable of measuring doses from zero to one roentgen measured in milliroentgen increments and provided with an audible indicator discernible above the ambient noise level; the direct reading dosimeter shall be read daily and doses shall be recorded in a log book; and

2. Portable radiation survey instruments capable of measuring the maximum radiation levels anticipated to be present at the facility and provided with an audible indicator discernible above the ambient noise level.

(i) The registrant shall ensure that the PASO assigns appropriate personnel monitoring equipment to each individual who works with the particle accelerator and that the use of such personnel monitoring equipment meets the requirements of N.J.A.C. 7:28-7.

(j) The registrant shall immediately confirm the radiation level measured by a personnel monitoring device if a direct reading dosimeter indicates exposure greater than 200 milliroentgens.

(k) The registrant shall maintain the personnel monitoring reports and the daily log records of the direct reading dosimeter values at the particle accelerator facility to insure compliance with N.J.A.C. 7:28-8. These records and logs shall be produced for review by the Department during an inspection and shall be submitted to the Department upon request.

7:28-20.12 Ventilation systems

The registrant of a particle accelerator shall ensure that the maximum permissible average concentration of radioactive materials in air and water shall be as specified in N.J.A.C. 7:28-6 and the concentration of radioactive materials in effluents from the controlled areas shall meet the requirement of N.J.A.C. 7:28-11.

7:28-20.13 Electron Microscopes

(a) Electron microscopes shall be exempt from the requirements of N.J.A.C. 7:28-20.4 through 7:28-20.12 except for the following requirements:

1. The registrant shall not use or cause an electron microscope to be used unless a radiation protection survey has been performed by an individual under the supervision of the PASO as defined in N.J.A.C. 7:28-20.4 to ensure compliance with N.J.A.C. 7:28-5 and 7 before the electron microscope is put into operation; the registrant shall submit a copy of the survey report to the Department within 30 days of the date of the survey and shall maintain the original survey report at the electron microscope facility; the survey report shall be produced for review by the Department during an inspection;

2. The electron microscope shall be resurveyed after every repair, modification, or relocation that would affect radiation exposure; the registrant shall submit a copy of the survey report to the Department within 30 days of the date of the resurvey and shall maintain the resurvey report at the electron microscope facility; the resurvey shall be produced for review by the Department during an inspection.

3. The registrant shall ensure that the electron microscope operating parameter indicators and controls pertinent to the production of radiation are clearly identified and easily discernible; the electron microscope shall be provided with a clearly visible label bearing the conventional radiation symbol and the words CAUTION: THIS EQUIPMENT PRODUCES X-RAYS WHEN ENERGIZED or other words having equivalent meaning affixed on the column.

4. The registrant shall provide each electron microscope operator with appropriate personnel monitoring equipment as required by N.J.A.C. 7:28-7 and require that the device be worn by each individual during operation of the electron microscope.

i. The registrant shall ensure that the personnel monitoring reports received from the personnel monitoring device processor contain the information required in N.J.A.C. 7:28-8; and

ii. The personnel monitoring reports received from the personnel monitoring device processor shall be maintained for inspection by the employee and the Department pursuant to the requirements of N.J.A.C. 7:28-8.

(b) Electron microscopes incapable of operating at 30 kVp or above shall be exempt from the requirements of N.J.A.C. 7:28-20.13(a)4 provided the initial or repeat radiation protection survey does not yield radiation levels using maximum conditions of operation as measured at five centimeters from any accessible surface greater than 0.5 millirem per hour.

(c) The registrant shall provide a means to secure the electron microscope to prevent unauthorized use when not in operation. Such means may include, but are not limited to, a locked console or locked room.

SUBCHAPTER 21. ANALYTICAL X-RAY INSTALLATIONS21. ANALYTICAL X-RAY INSTALLATIONS

7:28-21.1 Scope

(a) This subchapter applies to installations using analytical x-ray equipment and establishes requirements for their use.

(b) The provisions of this subchapter are in addition to, and not in substitution for, the other applicable provisions of this chapter.

7:28-21.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Analytical x-ray equipment" means any device or combination of devices used to determine the microcopic structure or composition of material utilizing x-rays, including but not limited to x-ray diffraction, x-ray spectroscopy, x-ray fluorescence, or fluorescence x-ray spectroscopy equipment.

"Enclosed beam x-ray system" means analytical x-ray equipment in which all possible x-ray paths are fully enclosed according to the requirements of N.J.A.C. 7:28-21.5, so that any part of the body cannot enter the enclosure.

"Fail-safe characteristics" means that all failures of warning and safety systems that can reasonably be anticipated will cause the equipment to fail in a mode such that personnel are safe from exposure to radiation.

"Open beam x-ray system" means analytical x-ray equipment other than enclosed beam x-ray system.

"Safety interlock" means a device or system of devices intended to prevent either the generation of x-rays or the emergency of the primary beam from the tube housing.

"X-ray accessory apparatus" means any portion of an analytical x-ray installation which is external to the x-ray tube housing and into which an x-ray beam is directed for making x-ray measurements or for other uses.

7:28-21.3 General equipment requirements

(a) No person shall cause, suffer, allow or permit the possession or use of any analytical x-ray equipment unless it is equipped with the following:

1. A clearly visible label bearing the conventional radiation symbol and the words: "CAUTION: THIS EQUIPMENT PRODUCES X-RAYS WHEN ENERGIZED—TO BE OPERATED ONLY BY AUTHORIZED PERSONNEL" or other words having similar meaning which shall be attached near any switch which energizes an x-ray tube.

2. A clearly visible label bearing the conventional radiation symbol and the words: "CAUTION: HIGH INTENSITY X-RAY BEAM" or other words having similar meaning which shall be located in a conspicuous location near the x-ray tube housing.

3. A clearly visible warning light with fail-safe characteristics labeled with the words: "X-RAY ON" or other words having similar meaning which shall be located near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized. The

provisions of this paragraph shall be effective February 1, 1980.

4. A clearly visible warning light or indicator with fail-safe characteristics which shall indicate when the x-ray tube is producing x-rays or the port of the radioactive source is open. The warning light or indicator shall be located in a conspicuous position near the x-ray tube, and shall be clearly visible to any person aligning or adjusting the x-ray accessory equipment. The provisions of this paragraph shall be effective February 1, 1980.

5. A clearly visible label bearing the conventional radiation symbol and the words: "CAUTION: THIS EQUIPMENT CONTAINS RADIOACTIVE MATERIAL—TO BE OPERATED ONLY BY QUALIFIED PERSONNEL" or other words having similar meaning which shall be attached to any switch which energizes analytical x-ray equipment which contains a radioactive source.

6. A clearly visible label which shall be attached to each radiation source housing that contains a radioactive source. The label shall include the following information:

   i. The conventional radiation symbol; and
   ii. The type of radioactive material; and
   iii. The activity in curies or millicuries; and
   iv. The date of measurement of activity.

(b) No person shall cause, suffer, allow or permit the possession or use of any analytical x-ray equipment unless such operation is in accordance with the following procedures and within the following dose rates:

1. Written operating and alignment procedures provided by the manufacturer of the x-ray system, or by the person in charge of use of the system if the radiation source housing and x-ray accessory apparatus are not compatible components supplied by the same manufacturer.

2. Written operating procedures shall be such that a qualified operator following instructions will not receive in any one hour a dose equivalent in excess of 37.5 mrem to the hands and forearms or 2.5 mrem to the whole body, gonads, blood-forming organs or lens of the eye.

3. Alignment procedures shall be such that a qualified worker aware of the radiation hazards will not receive in any one hour a dose equivalent in excess of 37.5 mrem to the hands and forearms or 2.5 mrem to the whole body, gonads, blood-forming organs, or lens of the eye while following these instructions. If either of these dose rates is likely to be exceeded, a definite warning shall be included in the alignment instructions.

4. The dose due to unwanted radiation from components such as high voltage rectifiers shall not exceed 10 mrem in a week in any accessible region 5 cm from the outside surface of the generator cabinet. Where an individual may be in the vicinity of the equipment while it is operating for as long as 40 hours per week, the dose rate shall not exceed 0.25 mrem/hr.

5. The x-ray accessory apparatus shall include a beam trap or other barrier with sufficient shielding so that the dose rate due to the transmitted primary beam does not exceed 0.25 mrem/hr under normal operating conditions. In the presence of scattered radiation this requirement shall be considered met for x-ray tube sources if the inherent shielding of the trap or barrier is at least equivalent to the thickness of lead specified in the following table for the maximum rated anode current and potential. In the case of isotope sources that required barrier thickness shall be determined by a qualified expert. Thickness of lead Required for a Primary Beam Barrier Located 5 cm from the Focal Spot

#

Anode Current	Thickness of lead (mm)		
(ma)	50 kVp	70 kVp	100 kVp
20	1.5	5.6	7.7
40	1.6	5.8	7.9
80	1.6	5.9	
160	1.7		

7:28-21.4 Additional equipment requirements for open beam x-ray systems

(a) No person shall cause, suffer, allow or permit the possession or use of any open beam analytical x-ray equipment unless it is equipped with the following in addition to the requirements of section 3 of this subchapter:

1. A clearly visible warning light or indicator which shall be located near each individual x-ray tube shutter and shall indicate when the shutter is open.

2. A suitable barrier to clearly delineate the boundary between the radiation area and the controlled area.

3. A system barrier surrounding each radiation area with sufficient inherent shielding so that the dose equivalent received by individuals in the surrounding controlled area does not exceed five mrem in any one hour or 100 mrem in any five consecutive days.

4. A beam shutter for each port of the radiation source housing. Such beam shutter shall be interlocked with the x-ray accessory apparatus coupling, or collimator, in such a way that the port will be open only when the collimator or coupling is in place. Shutters at unused ports shall be secured to prevent casual opening.

5. A guard or interlock which prevents entry of any part of the body into the primary beam path.

6. The provisions of paragraphs 3, 4 and 5 of this subsection shall apply to new open beam analytical x-ray equipment after February 1, 1980. Open beam analytical x-ray equipment in use prior to February 1, 1980 shall be exempt from the provisions of paragraphs 3, 4 and 5 unless such equipment is sold, leased, loaned or otherwise transferred from one user to another whether gratuitously or for consideration.

(b) No person shall cause, suffer, allow or permit the possession or use of any open beam analytical x-ray equipment unless it is operated in accordance with the following procedures and within the following dose rates:

1. The x-ray generator, the control panel and all other parts of the analytical x-ray system, except the x-ray tube housing, shall be so constructed that with all the shutters closed, the stray radiation measured at a distance of five centimeters from its surface is not capable of producing a dose in excess of 0.25 millirem in one hour at any specified tube rating.

2. The x-ray tube housing shall be so constructed that with all shutters closed, the leakage radiation measured at a distance of 5 centimeters from its surface is not capable of producing a dose in excess of 2.5 millirem in one hour at any specified tube rating.

3. Radiation exposure levels in the vicinity of controls and adjustments of the x-ray accessory apparatus used during routine operation shall not exceed 37.5 mrem/hr to the hands or 2.5

mrem/hr to the whole body, gonads, blood-forming organs, or lens of the eye.

7:28-21.5 Additional equipment requirements for enclosed beam X-ray systems

(a) No person shall cause, suffer, allow or permit the possession or use of any enclosed beam analytical x-ray equipment unless it is equipped with the following:

1. A sufficient number of safety interlocks so that the opening of any section of the enclosure during normal operation, or routine alignment, or routine maintenance will prevent either the generation of x-rays or the emergence of the primary beam from any x-ray tube housing port.

2. A chamber or coupled chambers to enclose the radiation source, sample, detector and analyzing crystal. Any such chamber shall be constructed so that it can not be entered by any part of the body during normal operation. The provisions of this paragraph shall be effective February 1, 1980.

3. A sample chamber closure which shall be interlocked with either the x-ray tube high voltage supply or with a shutter in the primary beam so that no x-ray beam can enter the sample chamber while it is open. Such interlock shall be of fail-safe design. The provisions of this paragraph shall be effective February 1, 1980.

(b) No person shall cause, suffer, allow or permit the possession or use of any enclosed beam analytical x-ray equipment unless it is constructed in such manner as to limit the leakage x-rays at a distance of 5 centimeters from any accessible surface during normal operation to less than 0.25 millirem in one hour at any specified tube rating.

7:28-21.6 Operating procedures

(a) No person shall cause, suffer, allow or permit the possession or use of any analytical x-ray equipment unless it is operated in accordance with the following procedures:

1. All safety devices, including but not limited to, warning lights, warning indicators, and safety interlocks as required by this subchapter shall be maintained in a fully functional operating condition. These safety devices shall be tested for proper functioning as recommended by the manufacturer or once every six months and records kept of all such testing.

2. All safety devices, including but not limited to, warning lights, warning indicators, and safety interlocks originally provided at the time of the installation of the analytical x-ray equipment, but not otherwise specified by this subchapter, shall be maintained in a fully functional operating condition. An exemption may be made, subject to the approval by the Department, when the operational procedures prohibit the normal functioning of these safety devices. Records of these exemptions shall be kept.

3. In addition to and not in substitution for the applicable requirements of subchapter 7 (Radiation Surveys and Personnel Monitoring) of this chapter, all personnel operating, repairing and aligning analytical x-ray equipment shall be provided with appropriate finger or wrist personnel monitoring equipment. The reported dose equivalent shall be recorded on Form BRP-26, "Current Occupational External Radiation Exposure," or on a clear and legible form containing all the information required on BRP-26. This reported dose equivalent shall be clearly identified as resulting from exposure to analytical x-rays.

4. A radiation survey shall be made before a new installation is placed in routine operation and whenever changes are made that could adversely affect radiation protection, as required by subchapter 7 (Radiation Surveys and Personnel Monitoring). Records shall be maintained showing the results of such surveys as required by subchapter 8 (Records) of this chapter.

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SUBCHAPTER 24. NUCLEAR MEDICINE TECHNOLOGY24. NUCLEAR MEDICINE TECHNOLOGY

7:28-24.1 Scope

The regulations in this subchapter establish radiation safety requirements for persons administering radiopharmaceuticals to humans for diagnostic or therapeutic purposes or performing diagnostic or therapeutic procedures requiring administration of radiopharmaceuticals or radioactive substances to humans. This subchapter shall not be construed to in any way confer authority upon nuclear medicine technologists to utilize sealed sources for purposes of radiotherapy.

7:28-24.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings unless the context clearly indicates otherwise.

"Act" means the Radiation Protection Act P.L. 1958, Chapter 116 as amended (N.J.S.A. 26:2D-1 et seq.).

"Approved school" means a school of nuclear medicine technology approved pursuant to this subchapter included on a list published by the department.

"Certificate" means a written authorization issued by the department pursuant to this subchapter.

"Direct supervision" means, for purposes of this subchapter, physical presence by the supervising physician or certified nuclear medicine technologist, in the room where a procedure is being performed, for a sufficient period of time to prevent unnecessary radiation to the patient.

"Initial application" means the first application submitted by an individual to the State for a license to practice nuclear medicine technology subsequent to completing the requirements in N.J.A.C. 7:28-24.4 and 7:28-24.5(a).

"License" means a written authorization issued by the department pursuant to this subchapter.

"License" means any person who is licensed or recognized by the department pursuant to this chapter and the act.

"Nuclear medicine technologist" means a person who performs technical procedures in the utilization of radionuclides or radiopharmaceuticals administered to humans.

"Physician" means an individual who upon having satisfied the requirements of the New Jersey State Board of Medical Examiners, has been issued a plenary license to practice medicine and surgery in this State.

"Radionuclide" means a radioactive element or a radioactive isotope.

"Radiopharmaceutical" means a radionuclide or radioactive compound designed and prepared for organ or body system administration.

NOTE: Definitions for other terms used in this subchapter may be found in subchapter 1 of this chapter.

7:28-24.3 Use of radionuclides and radiopharmaceuticals

(a) No owner or licensee shall cause, suffer, allow or permit any person to act as a nuclear medicine technologist unless such person has been issued a license as provided for by this subchapter.

(b) No person shall cause, suffer, allow or permit the use or application of radionuclides or radiopharmaceuticals or otherwise engage in the practice of nuclear medicine technology without having first satisfied the licensing requirements of this subchapter.

(c) The licensing requirements of this subchapter shall not apply to a hospital resident or intern who is specializing in nuclear medicine or to students enrolled in and attending a school or college of medicine, osteopathy or nuclear medicine technology provided such students are acting under the direct supervision of a physician or a licensed nuclear medicine technologist responsible to such physician.

(d) The licensing requirements of this subchapter shall not apply to hospital residents or interns involved in nuclear medicine procedures but not specializing therein provided that they are acting under the direct supervision of a physician or a licensed nuclear medicine technologist responsible to such physician under special circumstances.

7:28-24.4 Examination requirements

(a) In order to be eligible for admission to a licensing examination, an applicant must:

1. Have satisfactorily completed a course of study in an approved school; or
2. For a period of three years from the effective date of this subchapter become qualified in accordance with section 10 of this subchapter.

7:28-24.5 Licensing requirements

(a) In order to become licensed, an applicant shall be required to pass the licensing examination given pursuant to this subchapter, which may be written and, when deemed necessary by the department, may include proficiency testing. The department may waive the examination requirements for any applicant who has demonstrated competency by passing a national registry examination. The department may accept in lieu of its own exami-nation a certificate, registration, or license as a nuclear medicine technologist issued by another state; such acceptance will be based on standards in the other state being satisfactory to the department. All licensing examinations must be approved by the commission.

(b) A fee may be charged for each examination. The examination fee shall not be refunded. Application for the examination shall be made on a form supplied by the department which shall be filed, along with the examination fee, with the department no later than midnight of the closing date for the examination.

(c) An applicant who fails to pass the examination may reapply in accordance with the application provisions of this subchapter.

(d) Licenses issued by the department pursuant to this subchapter shall be displayed prominently in the work area utilized by the licensed nuclear medicine technologist.

7:28-24.6 Relicensing requirements

A license issued pursuant to this suchapter shall be renewed annually upon submission of a renewal application provided by the department and containing such information as the department deems necessary to show that the nuclear medicine technologist is in good standing.

7:28-24.7 Conditional license

(a) Any license issued pursuant to this subchapter may be conditional, as the department deems appropriate, including, but not limited to, a condition limiting the scope of the nuclear medicine practice authorized by such license.

(b) The department may issue temporary licenses to graduates of approved schools or to persons whose applications have been approved by the commission pursuant to N.J.A.C. 7:28-24.10.

(c) No person shall cause, suffer, allow or permit the breach of any condition of a license issued pursuant to this subchapter.

7:28-24.8 School approval

(a) The commission may approve a school of nuclear medicine technology if it meets the essentials or equivalent of an accredited education program as established by the American Medical Association Council on Medical Education in collaboration with the Society of Nuclear Medicine, The American Society of Radiologic Technologists, Ameican Society of Clinical Pathologists, and other collaboratory organizations.

(b) A school of nuclear medicine technology, in order to become an approved school, must apply to the department in writing on forms provided by the department. All such applications will be reviewed by the commission prior to final approval. A temporary approval may be issued by the department while an application is under review.

7:28-24.9 School curriculum and requirements

(a) An approved school must offer the following curriculum, as a minimum, for nuclear medicine technologists:

1. Basic anatomy, physiology, and pathology;
2. Intravenous injections and radiopharmaceutical toxicology;
3. Radiation physics and mathematics;
4. Instrumentation;
5. Radiation biology;
6. Radiation protection and radiation protection standards and codes;
7. Laboratory procedures and techniques (in vivo and vitro);
8. Clinical application of radionuclides, diagnostic and therapeutic;
9. Records and administrative procedures;
10. Medical ethics.

(b) In order to maintain approval, a school must:

1. Report in writing to the department the name and address of each new student enrolled within 30 days of such enrollment and (within 30 days the name and address of) each student who has successfully completed the course of study.

2. Limit the number of students enrolled so that the ratio of students to full time certified nuclear medicine technologists, to scanning equipment and to workload at the clinical facilities shall be reasonable.

3. Provide all students with a personal radiation monitoring service, such as dosimeter or badge, during their period of attendance. Student exposure to radiation shall not exceed the occupational limits prescribed by this chapter. Students shall routinely be informed of their most recent exposure readings and an attempt shall be made to find the cause and prevent

recurrence of exposure which is deemed to be unnecessary.

4. Issue to each candidate prior to admission a course catalog, bulletin, or other written statement which shall be dated, and include a description of the curriculum as a whole and the detailed courses offered, a listing of the faculty members with information regarding their qualifications, and information concerning amounts and terms for payment of any tuition or other fees or expenses to be incurred.

5. Insure that all students have on their person at all times while undergoing classroom or clinical training a readily identifiable uniform marking or coloration or identification name plate which indicates that they are students and not certified nuclear medicine technologists.

6. Not assign students excessive night or weekend experience. All night and weekend experience must be assigned only under adequate supervision and when sufficient education benefit may be derived from such service. Students shall not be assigned unsupervised night or weekend experience during their entire period of training.

7:28-24.10 Consideration of experience or training in lieu of attendance at an approved school

(a) Any person who believes he is qualified for a license pursuant to this subchapter based on training and/or experience in lieu of attendance at an approved school, may apply to the department for approval to take the license examination. The department will submit all applications to the commission for review prior to approval.

(b) Admission to the license examination pursuant to (a) above shall be permitted for a period of three years only from the effective date of this subchapter.

(c) Minimum requirements for consideration under this section shall include:

1. High school diploma or equivalent;
2. Two years of experience as a nuclear medicine technologist.

7:28-24.11 Nuclear medicine records

(a) A licensee, owner or registrant shall be responsible for recording such information as may be required as a condition of registration or licensing pursuant to this chapter. Such information may include, but is not limited to, the name of nuclear medicine technologist utilizing radionuclides or radiopharmaceuticals.

(b) A nuclear medicine technologist shall be responsible for recording the radionuclide or radiopharmaceutical dose he or she administers, and recording his name.

7:28-24.12 Revocation; penalties

(a) The department, in addition to any penalties authorized by the Act, may deny, suspend or revoke an application or license of a nuclear medicine technologist when the applicant or licensed nuclear medicine technologist has:

1. Falsified or made misleading statements in the application for a license;

2. Has altered his or her license;

3. Failed to keep or falsified any required records;

4. Failed to comply with any provision of the Act or any rules or regulations promulgated thereunder.

(b) The reasons for denial, suspension, revocation set forth in subsection (a) of this section shall be considered violation of these rules and act in addition to constituting grounds for denial, suspension or revocation.

7:28-24.13 Registration and licensing requirements

(a) The possession and use of radiopharmaceuticals are subject to the licensing requirements of N.J.A.C. 7:28-4.

(b) All owners of radiopharmaceuticals not subject to specific State licensing requirements, must register them in accordance with the requirements of N.J.A.C. 7:28-3.

7:28-24.14 Responsibility of physician

(a) Only a physician who has lawfully obtained a Federal or New Jersey State license as per N.J.A.C. 7:28-4, or is authorized under such a license, to own or possess or use radioactive substances, shall prescribe dosage, administer, or shall arrange for the administration of said substances to a human being or irradiate, or arrange for the irradiation of human beings by said substances.

(b) Any physician who arranges for the intentional human administration of, or irradiation by, radioactive substances shall be responsible for determining that only a certified nuclear medicine technologist or another qualified physician administers said radioactive substances.

(c) In addition, the physician must signify that he personally attests to the competency of the nuclear medicine technologist and must assume full responsibility for the intravenous injections by said technologist.

(d) A nuclear medicine technologist shall not apply or administer therapeutic doses of radionuclides or radiopharmaceuticals in any form to patients, although the actual material may be measured and prepared by the nuclear medicine technologist under the direction of a physician. The physician must personally determine the dose and administer the material to the patient.

(e) Only a physician who has lawfully obtained a Federal or New Jersey State license as per subchapter 5 of this chapter or who is authorized under such a license to own or possess or use radioactive substances, shall be permitted to supervise a nuclear medicine technologist. Such supervision shall require that such physician, acting within the limits specified in the laws under which he is authorized to use radioactive substances, shall determine that the administration of a radionuclide to a patient is appropriate and shall determine which radionuclide and what dosage level shall be used before such material is administered to the patient by the certified nuclear medicine technologist. Such supervision shall also require that only a physician shall receive the images and results of the examination performed after the administration of the radiopharmaceutical for the purpose of diagnostic interpretation. Such supervision shall not require that he oversee the certified nuclear medicine technologist in the measurement of doses, positioning of patients, operation of nuclear medicine instrumentation, injection of radionuclides or production and processing of images or test data.

7:28-24.15 Fees

(a) Any person who submits an application for a license, relicensing or license renewal to the department shall include as an integral part of said application a service fee as follows:

1. Application Fee: $40.00;
2. Renewal Fee: $20.00.

(b) The fees accompanying the application or annual registration renewal shall be in the form of a certified check or money order made payable to the State of New Jersey.

1. The fees submitted to the department are not refundable.
2. The applications or registrations and the fees accompanying them shall be mailed to:

State of New Jersey
Department of Environmental Protection
Bureau of Collection and Licensing Unit
CN 402
Trenton, New Jersey 08625

(c) The waiving of the written examination of any applicant whom the Commission on Radiation Protection has deemed competent will not result in any reduction of the fee for the license examination.

(d) The license issued pursuant to this subchapter shall be validated on an annual term commencing with January 1 of the year for which it is issued and expiring 12:00 midnight December 31 of the same year.

7:28-24.16 Unethical conduct

(a) No nuclear medicine technologist or student shall engage in any unethical conduct. Such conduct may include, but is not limited to:

1. Engaging in the practice of nuclear medicine technology while in an intoxicated state or under the influence of narcotic or any drugs which impair consciousness, judgement or behavior;

2. Willful falsification of records, or destruction or theft of property or records relating to the practice of nuclear medicine technology;

3. Failure to exercise due regard for the safety of life or health of the patient;

4. Unauthorized disclosure of information relating to a patient or a patient's records;

5. Discrimination in the practice of nuclear medicine technology against any person on account of race, religion, color or national origin.

7:28-24.17 Guidelines

The department may, from time to time, publish guidelines and/or procedural rules to explain and implement the various provisions of this subchapter.

SUBCHAPTER 25. RADIATION LABORATORY FEE SCHEDULE25. RADIATION LABORATORY FEE SCHEDULE

7:28-25.1 Scope

This subchapter establishes the Department's fee schedule for conducting various radioanalytical services in the monitoring of public water systems for radioactivity in accordance with the New Jersey Primary Drinking Water Regulations, N.J.A.C. 7:10-5.

7:28-25.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Gross alpha particle activity" means the total radioactivity due to alpha particle emission as inferred from measurements on a dry sample.

"Gross beta particle activity" means the total radioactivity due to beta particle emission as inferred from measurements on a dry sample.

"Public community water system" means a public water system which serves at least 15 service connections used by year-round residents or regularly serves at least 25 year-round residents.

"Public noncommunity water system" means a public water system that is not a community water system.

"Public water system" means a system for the provision to the public of piped water for human consumption, if such system has at least 15 service connections or regularly serves at least 25 individuals daily at least 60 days out of the year. Such term includes any collection, treatment, storage and distribution facilities under control of the operator of such system and used primarily in connection with such system, and any collection or pretreatment storage facilities not under such control which are used primarily in connection with such system. A public water system is either a "community water system" or a "noncommunity water system".

"Supplier of water" means any person who owns or operates a public water system.

"Water system" means a system for providing potable water to any person.

7:28-25.3 Terms and conditions for use of the State radiation protection laboratory radioanalytical services

(a) Any supplier of water wishing to utilize the State radiation protection laboratory for the purpose of monitoring a public water system for radioactivity shall apply, in writing, to the address listed below for a sample delivery schedule to be established by the State laboratory:

New Jersey Department of Environmental Protection
Radiation Protection Laboratory
CN 411
380 Scotch Road
Trenton, New Jersey 08625

(b) The laboratory shall provide appropriate containers to the suppliers of water for use in submitting water samples. No samples will be accepted without prior approval from the laboratory, and only those samples delivered in laboratory provided containers will be accepted and analyzed by the laboratory.

(c) Suppliers of water desiring priority analysis and reporting of water samples may request expedited services as follows:

1. Immediate testing, that is, analysis and reporting of results within the three to 25 day turnaround times specified in N.J.A.C. 7:28-25.4(b).

2. Emergency testing, that is, analysis and reporting of results within the one to 21 day turnaround times specified in N.J.A.C. 7:28-25.4(b).

3. The laboratory will charge an additional fee for such expedited analysis as provided in N.J.A.C. 7:28-25.4(a).

7:28-25.4 Fees for radioanalytical services

(a) The fees for radioanalytical services, priority analysis, and containers are as follows:

Test	Fee ($)
Gross Alpha	50.00
Gross Beta	50.00
Gross Alpha & Beta	60.00
Tritium	60.00
Radium-226	80.00
Radium-228	140.00
Iodine-131	130.00
Strontium-90	140.00
Cesium-134 and 137	100.00
Strontium-89 and 90	140.00
Uranium	180.00
Radon-222	20.00
Gamma-ray Spectroscopy	95.00

Priority Analysis
Immediate /+50 percent of prescribed fee per sample
Emergency /+100 percent of prescribed fee per sample

(b) The priority analysis turnaround times (in days from sample receipt by the Department) are as follows:

[2]

Test	Immediate Priority	Emergency Priority
Gross Alpha	5	2
Gross Beta	5	2
Gross Alpha & Beta	5	2
Tritium	4	2
Radium-226	25	18
Radium-228	12	8
Iodine-131	7	4
Strontium-90	25	21
Cesium-134 and 137	7	3
Strontium-89 and 90	25	21
Uranium	10	5
Radon-222	3	1
Gamma-ray Spectroscopy	5	1

7:28-25.5 Payment of fees

Payment of fees shall be made by check or money order, payable to "Treasurer, State of New Jersey", no later than 60 days following the date of the laboratory invoice, to the following address:

Department of Environmental Protection
Bureau of Revenue
CN 402
25 Scotch Road

Trenton, N.J. 08625

END OF IONIZING RADIATION SECTIONS